

Disclosure FOI Request Log Date range from 10/01/2012 to 09/30/2013 Report

Total Records: 9990

Control #	Recd Date / Due Date	Action Office	Signature/ Requester	Subject
2012-7044	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21455
2012-7045	10/01/2012 10/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	LAERDAL MEDICAL, STAVANGER, NORWAY - EIR, 483, CORR 06/20-23/2011
2012-7046	10/01/2012 10/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rita Choi George Mason Law & Economic Center	FINANCIAL CONFLICT WAIVERS, CDER AND CBER ADVISORY COMM MEETINGS - 1997 TO 2002
2012-7047	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21858 - LABELING (CERTIFIED)
2012-7048	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, MISSISSAUGA, ONTARIO, CANADA - EIR, 483, CORR 02/01/12 TO 07/31/12
2012-7049	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21455 - LABELING (CERTIFIED)
2012-7050	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EPIPEN - CORR RE MALFUNCTIONS OR EFFICACY
2012-7051	10/01/2012 10/30/2012	FDA/OF/CFSAN/OCD/EOS/	Maria Amodio ITTA	FCN 475
2012-7052	10/01/2012 10/30/2012	FDA/OF/CFSAN/OCD/EOS/	Maria Amodio ITTA	FCN 178

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2012-7053	10/01/2012 10/30/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF TOBACCO PRODUCTS MANUFACTURED, PREPARED, COMPOUNDED ETC THAT HAVE NOTIFIED FDA OF DISCONTINUANCE
2012-7054	10/01/2012 10/30/2012	ORA/ORM/ ORA/ORM/	Joseph Anderson Joseph Anderson	LIST OF DOMESTIC AND INTERNATIONAL INSPECTIONS - SPONSOR, MONITOR, CRO 01/01/1990 - 12/31/2011
2012-7055	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Takeda Global Research & Development Cen	ZYLOPRIM - AERS
2012-7056	10/01/2012 10/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Margaret Schumacher	GARDISIL - VAERS
2012-7057	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NEXT BREATH LLC, BALTIMORE, MD - EIR, 483, CORR 02/01/12-07/31/12
2012-7058	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PFIZER, INC, KALAMAZOO, MI - EIR, 483, CORR 02/01/12-07/31/12
2012-7059	10/01/2012 10/30/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NORWICH PHARM, NORWICH, NY - EIR, 483, CORR 02/01/12-07/31/12
2012-7060	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, INC, ONTARIO, CANADA - EIR, 483, CORR 02/01/12-07/31/12
2012-7061	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON, INC, ONTARIO, CANADA - EIR, 483, CORR 02/01/12-07/31/12
2012-7062	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 08/31/2012 - 09/27/2012
2012-7063	10/01/2012 10/30/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	UNIVERSITY OF IOWA, PHARM SERVICES DIVISION, IOWA CITY, IA - EIR, 483, CORR 02/01/12-07/31/12
2012-7064	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mary Lillian Walker Foltz Martin Hudson & Knapp, LLC	ISR 6545173, 7251443

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-7065	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	WEST ANALYTICAL SERVICES, LLC - MAUMEE, OH EIR, 483, CORR 02/01/12-07/31/12
2012-7066	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PHARMACEUTICS INTERNATIONAL, HUNT VALLEY, MD - EIR, 483, CORR 02/01/12-07/31/12
2012-7067	10/01/2012 10/30/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	HIGHSIDE CAPITAL MANAGEMENT	NUSKIN - INQUIRIES RE GALVANIC SPA DEVICE, AGELOC, ETC
2012-7068	10/01/2012 10/30/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MECOMM SOLUTIONS, EMERYVILLE, CA - EIR, 483, CORR 02/01/12-07/31/12
2012-7069	10/01/2012 10/30/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Doe J	TRIDENT SEAFOODS CORP, SEATTLE, WA - INSPECTION REPORTS, SAMPLE RESULTS, COMPLAINTS, ETC
2012-7070	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Derby Norphan Pharmaceuticals, Inc.	IND SPONSOR - DEFLAZACORT IN TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY
2012-7071	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Salinas Michael Salinas	LASIX - AERS
2012-7072	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ OM/OMP/DODM/	Iona Evans Labaton Sucharow LLP	VIROPHARMA - MEETINGS, MINUTES, CORR RE NDA 50606, AMENDMENTS, ACTION LETTER, ETC .

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2012-7073	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chloe Bird and/or Fabian Zaccardo PCCA	LIST OF FOREIGN IMPORTED DRUG PRODUCTS, LIST OF NDC NUMBERS
2012-7074	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Fort Lauderdale Sun-Sentinel Fort Lauderdale Sun-Sentinel	HCG - AERS
2012-7075	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet McChristion Fresenius Kabi LLC USA	ANDA 200837, 201048, 202563, ETC - APPROVAL LETTERS
2012-7076	10/01/2012 10/30/2012	CVM/OCD/	Kandarp Prajapati Advantagene Inc.	NADA 006475 - FOIA SUMMARY
2012-7077	10/01/2012 10/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Amlendu Prabhakar ARIZONA STATE UNIVERSITY	K875029
2012-7078	10/01/2012 10/30/2012	OM/OSS/OPILS/FDAHO/ OM/OMP/DODM/ OM/OMP/DODM/	NORWEGIAN UNIV OF SCIENCE AND TECHNOLOGY	FDA-NIMN PSYCHOTOMIMETIC AGENCY ADVISORY COMM - MEETING RECS 01/01/1967 - 12/31/1975
2012-7079	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahi Deligianis Mahi Deligiannis	08/01/96 LTR FROM DDMAC TO PFIZER RE ZOLOFT
2012-7080	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PHARMAGISTICS, LLC, SOMERSET, NJ - EIR, 483, CORR 02/01/12-07/31/12
2012-7081	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATHEON INC, BOURGOIN-JALLIEU, CEDEX, FRANCE - EIR, 483, CORR 02/01/12-07/31/12
2012-7082	10/01/2012 10/30/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PACE ANALYTICAL LIFE SCIENCES, LLC, OAKDALE, MN - EIR, 483, CORR 02/01/12-07/31/12

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2012-7083	10/01/2012 10/30/2012	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	UPS SUPPLY CHAIN SOLUTIONS (UNIT C&D), RENO, NV - EIR, 483, CORR 02/01/12-07/31/12
2012-7084	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	UPS SUPPLY CHAIN SOLUTIONS, LOUISVILLE, KY - EIR, 483, CORR 02/01/12-07/31/12
2012-7085	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	LANCASTER LABORATORIES, LANCASTER, PA - EIR, 483, CORR 02/01/12-07/31/12
2012-7086	10/01/2012 10/30/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	KNIPPER & CO, INC, LAKEWOOD, NJ - EIR, 483, CORR 02/01/12-07/31/12
2012-7087	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANJAY H SHARMA HETERO USA INC	ACTONEL (RISEDRONATE) (SODIUM) TABS - CHEMISTRY RVWS, BIOEQV RVWS, ADMINISTRATIVE RECS, ETC
2012-7088	10/01/2012 10/30/2012	FDA/OMPT/CTP/OD/	LILI SAWAN Sawan, Lili	CIGARETTES - LIST OF INGREDIENTS
2012-7089	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADRIENNE E FAERBER DARTMOUTH INSTITUTE	ARICEPT (DONEPEZIL) NDA 20-690 - APRVL LTR, MEDICAL RVWS, STATITICAL RVWS, ADMINISTATIVE RVWS, ETC
2012-7090	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	LABOR L & S AG, BAD BOCKLET-GROSSENBRACH, GERMANY - EIR, 483, CORR 02/01/12-07/31/12
2012-7091	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY LL GREEN ROCKY MOUNTAIN POISON DRUG CTR	COUGH & COLD PREPARATIONS - ISRS 8255706-3, 8259298-4, 8261197-9, ETC
2012-7092	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MICRONISIERUNGS-KONTOR OBERROT GMBH, OBERROT, GERMANY - EIR, 483, CORR 02/01/12-07/31/12

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2012-7093	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G CALEB ALEXANDER JOHN HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH	ABSTRAL(FENTANYL CITRATE) NDA 22-510; ACTIQ (FENTANYL CITRATE) NDA 20-747; BUTRANS (BUPRENOPHINE) NDA 21-306, ETC - EVALUATION, CORR, MEMOS, ETC
2012-7094	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	DR PREDRAG MINIC, BELGARDE, SERBIA 7/2-6/12; DR TORU SATOH, TOYKO, JAPAN 7/9-13/12; DR EKKEHARD GRUENIG, HEIDELBERG, GERMANY 7/23-27/12, ETC - EIRS, 483S, 482S, ETC
2012-7095	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GORDON, KAREN	MINOXIDIL - AERS
2012-7096	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	TRIAD, MACON, GA, MOBILE, AL, CHARLESTON, SC, ETC - EIRS, 483S
2012-7097	10/01/2012 10/30/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHN PAUL HUBBARD-HALL INC	HUBBARD-HALL INC, WATERBURY, CT - EIRS 10/13/10
2012-7098	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	NICHAEL NAZERIAS PETNET SOLUTIONS INC	BEAN APPLICATIONS, UNIONVILLE, NY; MCV MOLECULAR IMAGING CENTER, RICHMOND, VA, STERLING, VA, ETC - 483S
2012-7099	10/01/2012 10/30/2012	OC/COS/OL/ OC/OL/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO- FREE KIDS	FAMILY SMOKING & TOBACCO CONTROL ACT OF 2009 - CORR, REGULATIONS OF NICOTINE REDUCTION THERAPY PRODS 6/22/09 TO PRESENT
2012-7100	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	ROBERT, THOMAS	21 USC 321 SECTION 201 CHAPTER 2 DEFINITIONS I (G) (CERTIFIED)
2012-7101	10/01/2012 10/30/2012	FDA/OC/OES/DFOI/	GISSENDAMMER, ROBIN	483S - MOST RECENT 2012
2012-7102	10/01/2012 10/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Palmer Lambert Gainsburgh Benjamin c/o P. Lambert	BRILLIANT BLUE G COMPOUNDING AT FRANCK'S LAB, INC - INSPECTIONS, ENFORCEMENT RECS, CONTAMINATED LOTS, ETC

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2012-7103	10/01/2012 10/30/2012	OC/OM/OMP/DDM/	JONATHAN BERMAN JONES DAY	DKT 1978N-0038
2012-7104	10/02/2012 10/31/2012	OC/OM/OMP/DDM/	ROSS RENDELMANN HOGAN LOVELLS LLP	DKT FDA-2012-P-1028
2012-7105	10/02/2012 10/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Jenkins Law office of Sybil Shainwald	LYBREL - AERS
2012-7106	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K111136
2012-7107	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K120291
2012-7108	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	TeraRecon, Inc.	K083423
2012-7109	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K110070
2012-7110	10/02/2012 10/31/2012	FDA/OF/CFSAN/OCD/EOS/	Robert Weissman Saretsky Katz Dranoff & Glass, LLP	DMAA - INVESTIGATION, RECS RE POTENTIAL HARM, ADVERSE EVENT REPORTS, ETC
2012-7111	10/02/2012 10/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lisa Suchar LASamatovicz	VIVITROL - REVIEW PACKAGE FOR S015
2012-7112	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K091445
2012-7113	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 8/6-10/12
2012-7114	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 9/10-14/12
2012-7115	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 9/3-7/12
2012-7116	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/10-14/12
2012-7117	10/02/2012	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 9/3-7/12

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	10/31/2012		DOMINION GROUP INC	
2012-7118	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services, Inc.	FOI DAILY LOG 9/10-14/12
2012-7119	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services, Inc.	FOI DAILY LOG 9/3-7/12
2012-7120	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/10-14/12
2012-7121	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/3-7/12
2012-7122	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/10-14/12
2012-7123	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/3-7/12
2012-7124	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/10-14/12
2012-7125	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/3-7/12
2012-7126	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DYNAMIT NOBEL GMBH, KALKSTRASSE, LEVERKUSEN, GERMANY - 02/01/12-07/31/12
2012-7127	10/02/2012 10/31/2012	FDA/OC/OES/DFOI/	Christina Colla Christina Marie Colla	PHARMACEUTICAL COMPANIES - VIOLATIONS
2012-7128	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mendy Bolton Bolton, Mendy	ARMOUR THYROID - NONAPPROVAL DECISION RECS
2012-7129	10/02/2012 10/31/2012	FDA/OF/CFSAN/OCD/EOS/	Abigail Ross Keller and Heckman LLP	6/8/78 LTR FROM HW CHAO TO WL SCHLEYER; 5/22/61 LTR FROM FA CASSIDY RE CORROSION PREVENTATIVE IN WATER; ETC
2012-7130	10/02/2012	FDA/OMPT/CDER/GRP/DIDP/	David Lin	NDA 202736 - APPROVAL PACKAGE

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	10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BIOLOGICS CONSULTING GROUP	
2012-7131	10/02/2012 10/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	Nicola Kaiser IBL International GmbH	K102841
2012-7132	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hampus Rystedt BRANN AB	ALTU-237 - PRODUCT FILED BY ALTUS PHARM; ALLN-177 - PRODUCT FILED BY ALLENA PHARM
2012-7133	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNSON, CYNTHIA	FOSAMAX - AER
2012-7134	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS DeMELFI Jr. AMGEN	TOPOMAX NDA 20-505/S-022, 20-844, S-019 - APRVL, MEDICAL RVW, CHEMISTRY RVW
2012-7135	10/02/2012 10/31/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	RICHARD O. WOOD WOOD BURDITT GROUP	LEESAR REGIONAL SERVICE, FT MYERS, FL - 482, 483 LAST 5 YRS
2012-7136	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR. HONG SAJONZ Bayer HealthCare Pharmaceuticals	MULTIHANCE NDA 21-357/S011, NDA 21-358/S009
2012-7137	10/02/2012 10/31/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WILSON, MELISSA	JR CARLSON LABS - EIR, SUMMARY SPL QUESTIONS, CO RESP
2012-7138	10/02/2012 10/31/2012	FDA/OF/CFSAN/OCD/EOS/	MONTENEGRO, EBONY	CMPLNTS FROM SALON WORKERS
2012-7139	10/02/2012 10/31/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	BARRETT W. STETSON LAW FIRM OF BARRETT W STETSON	INDIVIDUAL RECS
2012-7140	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHEA N. SHAVER REILLY POZNER LLP	ZOLOFT (SERTRALINE HYDROCHLORIDE) NDA 19-839 - CORR 9/1/05 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7141	10/02/2012 10/31/2012	FDA/OF/CFSAN/OCD/EOS/	DANIEL A. EDELMAN EDELMAN COMBS LATTURNER ET AL	LANCOME USA, L'OREAL - CO RESP, CORR, EFFICACY 9/7/12
2012-7142	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALLEN D. NICKOL ACTELION CLINICAL RESEARCH INC	NOLVADEX NDA 17-970/S000 - APRVL
2012-7143	10/02/2012 11/13/2012	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/ OM/OMP/DODM/	THOMAS P. KELLY LAW OFFICES OF PETER G ANGELOS	COLGATE PALMOLIVE CO - REGULATIONS, GUIDELINES, VIOLATIONS REGARDING COSMETIC TALCUM POWDER PRODS, ETC
2012-7144	10/02/2012 10/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHAW, CARISSA	NOVARTIS - METHERGINE WARNING LABEL
2012-7145	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	CARL R NIELSEN C NIELSEN CONSULTING LLC	NANTONG TIANLONG ANIMAL BY-PRODUCTS CO LTD, JIANGSU, CHINA - EIRS, ANALYTICAL RPTS, CMPLNTS, ETC
2012-7146	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JASON G SHEASBY IRELL & MANELLA LLP	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) NON-CLNCL PHARMACOLOGY, TOXICOLOGY, HUMAN PHARMACOKINETICS, ETC
2012-7147	10/03/2012 11/01/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	ROBERT J KING JR LOMMEN ABDO COLE KING STAGEBERG PA	ABBOTT LABS - CMPLNTS, INSPS, ETC; INDIVIDUAL RECS
2012-7148	10/03/2012	FDA/OMPT/CDER/GRP/DIDP/	MCKENZIE CATO	OFFICE OF GENERIC DRUGS - 180-DAY EXCLUSIVITY

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	11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hyman, Phelps & McNamara, P.C.	2000-2012
2012-7149	10/03/2012 11/01/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	BRINKHOFF & MONOSON INC - ARCHER FARMS BRAND GROUND TURMERIC RECALL LOTS 1740901A, 2180902A, 2780906A, ETC
2012-7150	10/03/2012 11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	MARCIA L BENEDICT STERIS CORP	STERRAD NX DUO CYCLE TEST PACK K111391; STERRAD CYCLESURE 24 BIOLOGICAL INDICATOR K111375; STERRAD 100NX STERILIZER DUO CYCLE K1113777, ETC
2012-7151	10/03/2012 11/01/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	TYLER KENYON NORTHCOAST RESEARCH	ZIMMER HOLDING, PONCE, PR - WARNING LTR 9/21/12
2012-7152	10/03/2012 11/01/2012	FDA/OF/CFSAN/OCDE/EOS/	DR PETER D FOSTER HUHTAMAKI INC	JOHNSON POLYMERS - STYRENE-ACRYLIC COPOLYMERS FCN 130, FCN 231
2012-7153	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103772/S5113
2012-7154	10/03/2012 11/01/2012	OC/OOPD/	Daven Mody Impax Laboratories, Inc.	NEURONEX INTRANASAL DIAZEPAM - ORPHAN DRUG DESIGNATION RECS
2012-7155	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA202811
2012-7156	10/03/2012 11/01/2012	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Daven Mody Impax Laboratories, Inc.	BOTOX, BENEFIX, GRALISE, ETC - ORPHAN DRUG DESIGNATION/EXCLUSIVITY RECS
2012-7157	10/03/2012 11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	Anne Mitchell Mitchell, Anne	RENAL SHOCKWAVE LITHOSTRIPSY - ADVERSE EVENTS
2012-7158	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA LOG 07/01/2012 to 09/30/2012
2012-7159	10/03/2012 11/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Louise Miller LRT Trading	STATENS SERUM INSTITUT, COPENHAGEN, DENMARK - INSPECTION RECS, RECALLS, CONSENT DECREE ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-7160	10/03/2012 11/01/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PFIZER, GROTON, CT - EIR, 493, CORR 05/04/09
2012-7161	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/17-21/2012
2012-7162	10/03/2012 12/14/2012	FDA/OF/CFSAN/OCD/EOS/	Richard Henrich Chemtura Corporation	FCN 1152
2012-7163	10/03/2012 11/01/2012	FDA/OF/CFSAN/OCD/EOS/	Avery Hartley Avery Hartley	AQUAFINCA ST PETER FISH, HONDURAS - COMPLAINTS, INSPECTION REPORTS
2012-7164	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Linda Mota Shire Development LLC	BLA 103772, S5113; NDA 22000, S005; NDA 202811
2012-7165	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HOLLINGSWORTHLLP	AMERICAN HOME PRODUCTS - WARNING LETTER 02/14/92
2012-7166	10/03/2012 11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	COVIDIEN	K120657
2012-7167	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-6560
2012-7168	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Myers ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	ADENOSCAN - SBA
2012-7169	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Wagner BIOPHARM DEVELOPMENT ASSOCIATES, LLC	NDA 202811 - REVIEWER REPORTS

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2012-7170	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Myers ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	ADENOCARD IV - SBA
2012-7171	10/03/2012 11/01/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	INC RESEARCH CONSULTING & SUBMISSIONS	PFIZER, GROTON, CT - EIR, 483, CORR 10/14/10
2012-7172	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 9/1/12-9/30/2012
2012-7173	10/03/2012 11/01/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 9/24-28/2012
2012-7174	10/03/2012 11/01/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22000/S5
2012-7175	10/04/2012 11/02/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Richard O. Wood WOOD BURDITT GROUP	FLORIDA BIOLOGIX, ALUCHUA, FL - 482, 483, CORR ETC
2012-7176	10/04/2012 11/02/2012	FDA/OC/OES/DFOI/	Dr. Shiels / Amanda Bundy Children's Radiological Institute	FDA DRUG BULLETIN FDA JULY 1989;15-16
2012-7177	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID PULLMAN Pullman, David	STATINS - AERS
2012-7178	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125360 S007
2012-7179	10/04/2012 11/02/2012	FDA/OMPT/CTP/OD/	KEVIN ALDRIDGE Aldridge, Kevin	LIST OF APPROVED CIGARETTE TUBE MANUFACTURERS FOR RYO
2012-7180	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura F. Hron Law Office of Joel M. Fineberg	EPOGEN/PROCRIT - APPROVAL LETTER

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2012-7181	10/04/2012 11/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OES/ OC/COS/OES/	Tom Burton THE WALL STREET JOURNAL	REPORT FOR OFFICE OF SPECIAL COUNSEL RE SAFETY OF MEDICAL DEVICES INCLUDING COLONAGRAPY
2012-7182	10/04/2012 11/02/2012	FDA/OF/CFSAN/OCD/EOS/	Elizabeth Metcalf Morgan & Morgan, P.C.	SUAVE PROFESSIONALS KERATIN INFUSION KIT - COMPLAINTS, COMMUNICATIONS WITH UNILEVER
2012-7183	10/04/2012 11/02/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	The Windward Company	ISIS SERVICES, SAN CARLOS, CA - EIR 03/22/11-04/07/11
2012-7184	10/04/2012 11/02/2012	FDA/OMPT/CDRH/OCER/DFOI/	Beverly Morrison Morrison, Beverly	K061011
2012-7185	10/04/2012 11/02/2012	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Robert McLennan Oregon Heritage Farms	SAMPLE 770367 - ANALYTICAL RESULTS
2012-7186	10/04/2012 11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kimberly Calandriello	VENLAFAXINE ER, EFFEXOR XR - AERS
2012-7187	10/04/2012 11/02/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CenterWatch Monthly	NUMBER OF CLINICAL HOLDS APPLIED TO CLINICAL RESEARCH STUDY OR NEW DRUG APPLICATION DUE TO MISLEADING OR INCOMPLETE INVESTIGATOR BROCHURE
2012-7188	10/04/2012 11/02/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Richard O. Wood WOOD BURDITT GROUP	ORGAN RECOVERY SYSTEMS, ITASCA, IL - INSPECTION RECS
2012-7189	10/04/2012 11/02/2012	CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Horace Nalle Oriole Animal Health LLC	STUDIES OF SAFETY OR EFFICACY OF IBUPROFEN AND FAMOTIDINE IN DOGS
2012-7190	10/04/2012 11/02/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Avery Hartley Avery Hartley	TRIDENT SEAFOODS CORP - TEST RESULTS 2005 TO PRESENT
2012-7191	10/04/2012	FDA/OGROP/ORA/CE-FO/CHI-	NIDIA NOEL	ABBOTT LABS, NORTH CHICAGO, IL - EIR MOST RECENT

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	11/02/2012	DO/CHI-CB/	EZEM CANADA	
2012-7192	10/04/2012 11/02/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JANET A. McCORMICK INTERIOR ALASKA FISH PROCESSORS INC	YUKON RIVER GOLD, KALTAG, AK - EIR 2007 TO 2010
2012-7193	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRITTANY LaPOINTE DISCOVERY RESOURCE LITIGATION SUPPORT SERVICES	ZOLOFT - APRVL
2012-7194	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ OM/OMP/DODM/	JAMES R.M. HEMMINGS SIDLEY AUSTIN LLP	DKTS 2007P-0358/CPI; FDA-2007-P-0111; 2007D-0168
2012-7195	10/04/2012 11/02/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/ OC/OCC/	WHITE, ROBERT W	PAXIL, DEPAKOTE, WELBUTRIN - OFF-LABEL PROMOTIONS, INVESTIGATION RECS REGARDING CHILDREN, TEENS, ETC
2012-7196	10/04/2012 11/02/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALISON M. AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	INSULET CORP - OMNIPOD SINCE 2009
2012-7197	10/05/2012 11/05/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OF/CFSAN/OCD/EOS/	Becky Cooseman Brown & Crouppen, PC	INDIVIDUAL RECS
2012-7198	10/05/2012 11/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OO/	Doe J	INDIVIDUAL RECS

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		FDA/OO/OHR/		
2012-7199	10/05/2012 11/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert E. Shapiro, MD, PhD UNIVERSITY OF VERMONT	ISRS 45767436, 4621628X, 65601858, 65985025
2012-7200	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Yves Arramon SpinalMotion	K110632
2012-7201	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Shawn Esmaili Cercacor Labs	K112638
2012-7202	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Yves Arramon SpinalMotion	K112036
2012-7203	10/05/2012 11/05/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	GE HEALTHCARE, SOUTH PLAINFIELD, NJ - EIRs 5/10/10, 3/10/11
2012-7204	10/05/2012 11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kerry King Intertox, Inc.	K932868
2012-7205	10/05/2012 11/05/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	BRACCO DIAGNOSTICS, PRINCETON, NJ - EIRs, 483s 3/11, 7/12
2012-7206	10/05/2012 11/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alison Stuebe UNC School of Medicine	METHERGINE - AERS
2012-7207	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	2012-6487
2012-7208	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	2012-6270
2012-7209	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	2012-5921
2012-7210	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	2012-5686
2012-7211	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	2012-5601
2012-7212	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	2012-5604

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2012-7213	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5307
2012-7214	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-3134
2012-7215	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-6515
2012-7216	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-6271
2012-7217	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-4694
2012-7218	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	2012-5841
2012-7219	10/05/2012 11/05/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHN WALSH JAMES ALEXANDER CORP	CARE FUSION, EL PASO, TX - EIRS, 483S, RECALLS 10/10 TO PRESENT
2012-7220	10/05/2012 11/05/2012	FDA/OC/OES/DFOI/	ROBERT A DORMER Hyman Phelps and McNamara PC	2012-5550, 2012-5647, 2012-6560, ETC
2012-7221	10/05/2012 11/05/2012	FDA/OF/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	METHYL GLUCOSIDE COCONUT OIL ESTER (METHYL GLUOCSE SEQUICOCOATE) - CHEMICAL & PHYSICAL PROPERTIES, METABOLISM/BIOAVL, DERMAL PENETRATION, ETC
2012-7222	10/05/2012 11/05/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	ANN K RITTER MOTLEY RICE LLC	AMERISOURCE BERGEN CORP, FL - VIOLATION OF FDA AMENDMENTS ACT OF 2007 ; BELLCO DRUG CORP (AMERISOURCE BERGEN CORP) 2008 - EIRS
2012-7223	10/05/2012 11/05/2012	FDA/OF/CFSAN/OCD/EOS/	JAMES H HARTTEN ARENT FOX LLP	LANCOME USA - RESP TO WARNING LTR 9/7/12
2012-7224	10/05/2012 11/05/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBIN WINCHESTER KESSLERTOPAZ MELTZERCHECK LLP	QUESTCOR PHARMACUTICALS INC - HP ACTHAR GEL EIRS, WARNING LTRS, APRVL, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ OC/OOPD/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/		
2012-7225	10/05/2012 11/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pam Brennan Pam Brennan	METHERGINE - AERS
2012-7226	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jay Sirois CONSUMER HEALTHCARE PRODUCTS ASSOCIATION	ACETAMINOPHEN - MEDWATCH REPORTS
2012-7227	10/09/2012 11/06/2012	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OF/CFSAN/OCD/EOS/	Nicole Palen EMSL Analytical, Inc.	SAMPLE RESULTS
2012-7228	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - CAERS 07/01/2011 - 08/31/2012
2012-7229	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barry Weathers Barry E. Weathers	DEPO MEDROL - COMPLAINTS, CORR, AERS, ETC
2012-7230	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden America, Inc.	K071969
2012-7231	10/09/2012 11/06/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ ORA/ ORA/	DeAnne Brooks THE MOSES H. CONE MEMORIAL HOSPITAL	AMERIDOSE, WESTBOROUGH, MA - MOST RECENT EIR, 483
2012-7232	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	Donald Ecklund CARELLA BYRNE BAIN ET AL	LANCOME, L'OREAL - RESPONSE TO WL ISSUED 9/7/2012

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2012-7233	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barry Necaise CBC Inc	K060656
2012-7234	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kathy Simpson Celleration, Inc.	K112782
2012-7235	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Irina Rivkind Irina Rivkind/Cantor Fitzgerald	JAZZ PHARMACEUTICALS - RESPONSE TO WARNING LETTER ISSUED 10/11/11
2012-7236	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	Matt Zepnick The Edelsteins, Faegenburg & Brown, LLP	TRANS1 AXIALIF 2L ANTERIOR SPINAL FIXATION MODEL NUMBER TR1-2316, EVENT DATE: 2/8/10; TRANS1 AXIALIF 2L ANTERIOR SPINAL FIXATION MODEL NUMBER TR1-2305, EVENT DATE: 11/23/09 - MAUDE REPORTS
2012-7237	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jim Peace Peace, Jim	DHEA - AERS
2012-7238	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	STACI M TROLIAN BIOMET INC	DR STEVEN MARK TRAINA - WARNING LTR CORR
2012-7239	10/09/2012 11/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	DENISE RIEKER SANOFI PASTEUR	VAERS - INDIVIDUAL RECS
2012-7240	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 155912
2012-7241	10/09/2012 11/06/2012	ORA/ORM/ ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL FACILITIES IN AND OUTSIDE THE US - 483S 9/1-30/12
2012-7242	10/09/2012 11/06/2012	OM/OMP/DODM/	MELISSA CERASO INFOTRIEVE INC	ANTIVIRAL A/C MTG - FIAU TOXICITY TRANS
2012-7243	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/OIP/	SHERRIE A IRELAND FLASTER GREENBERG	FATTORIE CHIARAPPA SRL - FRESCOLINA SALATA CHEESE LISTERIA OUTBREAK RECALL RECS, TESTING, CORR, ETC

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		ORA/ ORA/ FDA/OC/OES/DFOI/ ORA/ORO/DFS/ ORA/ORO/DFS/		
2012-7244	10/09/2012 11/15/2012	FDA/OC/OES/DFOI/	ROABERT P CHARROW GREENBERG TRAURIG LLP	MEDTRONIC XOMED INC - LASER-SHIELD II ENDOTRACHEAL TUBE; LASER ENGINEERING INC - ULTRA MD 40 LASER SYS RECS
2012-7245	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	CARLA R SCARMAZZI KING & SPALDING	CITREM (CITRIC ACID ASTERS OF MONO- AND DIGLYCERIDES), MAGNESIUM L-ASPARTATE - RECS
2012-7246	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHI WAI NG MEDICAL DEVELOPMENTS INTERNATIONAL LTD	METHOXYFLURANE - AERS
2012-7247	10/09/2012 11/06/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SHERI P COVINGTON K&L GATES	ACCUPAC, MAINLAND, PA - EIRS, 483S, WARNING LTRS, ETC 9/10 TO PRESENT
2012-7248	10/09/2012 11/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	KAREN E PETERSON ENTELLUS MEDICAL	ENTRIGUE SURGICAL INC - ENTRIGUE SINUS DILATION SYS K121351
2012-7249	10/09/2012 11/06/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL H LEVI PAUL WEISS RIFKIND WHARTON & GARRISON	SCIELE PHARMA INC, SHIONOGI PHARMA INC, SHIONOGA INC - REGULATORY MTG NOTES, MINS 1/07 TO 12/10, CMPLNT
2012-7250	10/09/2012 11/06/2012	ORA/ ORA/ ORA/OE/ ORA/OE/	WILSON, DAWN	NUMBER OF LEVEL 1 RECALLS 2007-2012
2012-7251	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 9/1- 31/12
2012-7252	10/09/2012 11/06/2012	ORA/ ORA/	SAMANTHA MYERS ROANOKE TRADE SERVICES INC	G & G PRODUCE LLC - ENTRY #BYX00430680 FDA NOTICE OF ACTION, INVOICES, BILLS OF LADING, ETC

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		FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/SWID/SWID-CB/		
2012-7253	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VASSLLIOS CHRISTODOULOPOULOS SANDOZ CANADA INC.	NDA 202-872 - RECS
2012-7254	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORAP-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORAP-FO/SAN-DO/SAN-CB/	RICHARD WANG TENZING GLOBAL	NU SKIN ENTERPRISES - AGELOC CMLPTS, INVESTIGATION
2012-7255	10/09/2012 11/06/2012	FDA/OO/OFBA/OAGS/	KIMBERLY LEGROW GRYPHON SCIENTIFIC	SOLICITATION FDA-12-223-SOL-00058 - PROPOSAL RVW PANEL RATING, NOTES
2012-7256	10/09/2012 11/06/2012	FDA/OGROP/ORAP-FO/SEA-DO/SEA-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS INC, KENT, WA - EIR, 483 2/12
2012-7257	10/09/2012 11/06/2012	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - FOREIGN AND DOMESTIC INSPS 8/1-31/12
2012-7258	10/09/2012 11/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY GREEN ESQ GREEN LAW FIRM PC	METHERGINE (METHYLERGONOVINE MALEATE) - AERS, LBLG, STORAGE RECS
2012-7259	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	BLACK COHOSH, SOY ISOFLAVONES - CAERS
2012-7260	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	PRIVATE-LABEL MENOPAUSE DIETARY SUPPLEMENT PRODS - CAERS
2012-7261	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	ONE-A-DAY WOMEN'S MENOPAUSE FORMULA DIETARY SUPPLEMENT PRODS - CAERS
2012-7262	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/	TODD A HARRISON VENABLE LLP	ESTROVEN, ESTROVEN MAXIMUM STRENGTH, ESTROVEN NIGHTTIME, ETC - CAERS
2012-7263	10/09/2012	FDA/OF/CFSAN/OCD/EOS/	TODD A HARRISON	REMIFEMIN, REMIFEMIN GOOD NIGHT - CAERS

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	11/06/2012		VENABLE LLP	
2012-7264	10/09/2012 11/06/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TODD A HARRISON VENABLE LLP	BLACK COHOSH, SOY - CAERS
2012-7265	10/09/2012 11/06/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/17-21/12
2012-7266	10/10/2012 11/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tyrah L. Miles DJA Global Pharmaceuticals, Inc	ZOMIG - SBA
2012-7267	10/10/2012 11/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tu Tu CSL BEHRING	NDA 020304 - SBA
2012-7268	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Elisabeth Neely St. Jude Medical	P840001/S185
2012-7269	10/10/2012 11/07/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Makit apS Makit apS	K021356
2012-7270	10/10/2012 11/07/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	North Dallas Honey Company, LP	NORTH DALLAS HONEY CO - COMPLAINT
2012-7271	10/10/2012 11/07/2012	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Travis Siverson BIRCHWOOD LABORATORIES INC	HYDROX CHEMICAL CO, ELGIN, IL - WARNING LETTERS, 483, RECALL, ETC01/01/2008 - 12/31/2009
2012-7272	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Richard O. Wood the Wood Burditt group	CDRH PROMOTION AND ADVERTISING UNTITLED LETTERS 01/01/2010 - 10/09/2012
2012-7273	10/10/2012 11/07/2012	ORA/ ORA/	Econ One Research	OFFICIAL ESTABLISHMENT INVENTORY RECORDS FOR INDUSTRY CODE 59
2012-7274	10/10/2012 11/07/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ ORA/ ORA/	Aaron Pressman Reuters News	NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA - WARNING LETTER FOLLOW UP RECS
2012-7275	10/10/2012	FDA/OMPT/CDRH/OCER/DFOI/		SHASTA TECHNOLOGIES - CORR WITH FDA RE GENSTRIP

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	11/07/2012	OC/COS/OES/ OC/COS/OES/ OC/COS/OL/ FDA/OC/OES/DFOI/	Lathrop & Gage LLP	ETC
2012-7276	10/10/2012 11/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Richard O. Wood the Wood Burditt group	CBER PROMOTION AND ADVERTISING UNTITLED LETTERS 01/01/2010 - 10/09/2012
2012-7277	10/10/2012 11/07/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	JOHNSON, JILL	ARKION LIFE SCIENCES, NEW CASTLE, DE - 483 4/11 TO PRESENT
2012-7278	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JOHNSON, JILL .	STERLING TECHNOLOGIES, BROOKINGS, SD - 483 4/11 TO PRESENT
2012-7279	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNSON, JILL .	APS BIOGROUP, PHOENIX, AZ - 483 4/11 TO PRESENT
2012-7280	10/10/2012 11/07/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	JOHNSON, JILL .	LEGACY FOR LIFE, OKLAHOMA CITY, OK - 483 4/11 TO PRESENT
2012-7281	10/10/2012 11/07/2012	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	JOHNSON, JILL .	VMI NUTRITION, SALT LAKE CITY, UT - 483 4/11 TO PRESENT
2012-7282	10/10/2012 11/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNSON, JILL	SOFTGEL TECHNOLOGIES INC, LOS ANGELES, CA - 483 4/11 TO PRESENT
2012-7283	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNSON, JILL .	AMERICAN COPAK CORP, CHATSWORTH, CA - 483 4/11 TO PRESENT
2012-7284	10/10/2012 11/07/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	SUSAN B. MILLS WEINBERG WHEELER ET AL	NATIONAL BEEF CALIFORNIA LP - EIR 1/09 TO PRESENT
2012-7285	10/10/2012 11/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	AHEARN, DONALD	IMMUNEX CORP - ENBREL ENTANERCEPT AER
2012-7286	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCC/	HENSON SR., J. DONALD	MTG BETWEEN J DONALD HENSON CDRH AND CHIEF COUNSEL - DOCUMENTATION OF CONVERSATION 7/03/12

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2012-7287	10/10/2012 11/07/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	ELENA HOWELL HOGAN LOVELLS LLP	HALEDEMAN MILLS, MANHEIM, PA - YELLOW CORN MEAL RECALL
2012-7288	10/10/2012 11/07/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	DONLAD N. BLUE ZETETIC INC	2 SOAP - ENTRY NO BGK- 0387652
2012-7289	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	GREGORY H. LEVINE ROPES & GRAY LLP	GEN1100033
2012-7290	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ OC/COS/OES/ OC/COS/OES/	MICHELLE JONES BURLESONS PURE HONEY	NATURE NATES HONEY, FRISCO, TX - FINES, JUDGEMENTS, CORR, ETC 3/30/12 TO 10/5/12
2012-7291	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY A/C MTG RE PELVIC MESH 9/8/11
2012-7292	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY MEDICAL DVCS A/C 9/8/11 - JOURNAL ARTICLES, DATABASES, SPREADSHEETS, ETC
2012-7293	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY MEDICAL DVCS A/C 9/8/11 - JOURNAL ARTICLES, DATABASES, SPREADSHEETS, ETC
2012-7294	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DAVID A. BORESI THURMAN LAW FIRM	MEDTRONIC INC - INFUSE BONE GROWTH ACCELERATOR PROD MDRS. CLNCL TRIAL RECS, PROTOCOLS, ETCPRO
2012-7295	10/10/2012 11/07/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SUSAN B. MILLS WEINBERG WHEELER ET AL	NATIONAL BEEF PACKAGING CO LLC - EIR 1/09 TO PRESENT
2012-7296	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M. MIRACLE HILL ROM	K863047; K914351; K915779
2012-7297	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M. MIRACLE HILL ROM	K921168; K926140; K944779
2012-7298	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	McKENZIE CATO Hyman, Phelps & McNamara, P.C.	SENTEHEART INC - LARIAT II SUTURE DELIVERY DEVICE K090385
2012-7299	10/10/2012 11/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	MATTHEW A. ZEPNICK EDELSTEINS FAEGENBURG & BROWN LLP	INDIVIDUAL RECS
2012-7300	10/10/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JEANETTE GOOGE	MORTON SLT INC, SOUTH HUTCHINSON, KS - 483, EIR MOST RECENT

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	11/07/2012		MORTON SALT INC	
2012-7301	10/10/2012 11/07/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATTHEW VENTRESCA MCMASTER UNIVERSITY	CODEINE USE IN CHILDREN - AERS
2012-7302	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	Surveyor Capital	BAXTER INTERNATIONAL INC, BAXTER HEALTHCARE CORP - 483 01/01/2009 - 10/04/2012
2012-7303	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	Fred Mamoun Fox Five News New York	JERKY PET TREATS - INSPECTIONS, COMPLAINTS 01/09/2007 - 10/09/2012
2012-7304	10/11/2012 11/08/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/COS/OES/ OC/COS/OES/	T. Christian Miller PROPUBLICA	MCNEIL CONSUMER HEALTHCARE - CORR TO FDA 05/01/2009 - 08/30/2009
2012-7305	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EPOGEN - APPROVAL RECS
2012-7306	10/11/2012 11/08/2012	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	NITRIC OXIDE - ORPHAN DRUG DESIGNATION
2012-7307	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA LOG 09/24/2012 - 10/05/2012
2012-7308	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Emily Bartkowicz AKERMAN SENTERFITT ATTYS	PELVIC MESH PRODUCTS - INVESTIGATION RECS, ANALYSIS
2012-7309	10/11/2012	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson	FCN 524, FAP 9B3477

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	11/08/2012		FOI Services, Inc.	
2012-7310	10/11/2012	FDA/OMPT/CDER/GRP/DIDP/	Daniel Casaburi	NDA 21-847
	11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NPS PHARMACEUTICALS	
2012-7311	10/11/2012	FDA/OF/CFSAN/OCD/EOS/		TRUEHOPE EMPOWERPLUS - AERS
	11/08/2012		CBC (AMERICA) CORP	
2012-7312	10/11/2012	FDA/OMPT/CTP/OD/	Kevin Aldridge	LIST OF REGISTERED CIGARETTE TUBE MANUFACTURERS
	11/08/2012		Aldridge, Kevin	
2012-7313	10/11/2012	FDA/OMPT/CDER/GRP/DIDP/	T. Christian Miller	JOHNSON & JOHNSON - MEETING MINUTES, AGENDAS, BRIEFING MATERIALS ETC FOR 02/19/2010 MTG WITH FDA
	11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	PROPUBLICA	
2012-7314	10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne	K092318
	11/08/2012		Ellipse Technologies, Inc.	
2012-7315	10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	Samantha Sledd	K042800
	11/08/2012		Hall & Sethi, PLC	
2012-7316	10/11/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TORREY COPE	KIMBERLY-CLARK CORP, ROSWELL, GA - CMPLNTS, FOI REQUESTS, INSPS, ETC 3/20/10 TO 10/5/12
	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/ FDA/OC/OES/DFOI/	SIDLEY AUSTIN LLP	
2012-7317	10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON M AGNEW	ABIOMED INC - IMPELLA DVC PROJECT II TRIAL STATISTICAL ANALYSIS PLAN
	11/08/2012		PILLSBURY WINTHROP SHAW PITTMAN LLP	
2012-7318	10/11/2012	OM/OMP/DODM/	JAMES C MINGEE	GENERIC DRUG USER FEE AMENDMENTS MTG - TRANS 9/21/12
	11/08/2012		MINGEE & ASSOCIATES	
2012-7319	10/11/2012	FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER	DVC REGISTRATION AND LISTING DATABASE 2012
	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOLEY & LARDNER LLP	
2012-7320	10/11/2012	FDA/OGROP/ORA/SW-FO/DAL-		INDIVIDUAL RECS

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	11/08/2012	DO/DAL-CB/ ORA/OCI/ ORA/OCI/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CONORS, ANTHONY ROBERT	
2012-7321	10/11/2012 11/08/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	GARY C COOPER GARY C COOPER LAW OFC	ENTRY #D52-0940626-8 - LAB RESULTS
2012-7322	10/11/2012 11/08/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WOODS 10B2776, LEON	PIREXICAM - AERS
2012-7323	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MICHELLE L MEJIA SANDLER TRAVIS & ROSENBERG PA	PERISHABLE SPECIALIST INC - ALL-0115379-0, ALL-0115922-7 NOTICES OF ACTION,REDELIVERY REQUESTS; SPIECH LLC - REFUSALS
2012-7324	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/ ORA/ ORA/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	MICHELLE L MEJIA SANDLER TRAVIS & ROSENBERG PA	DEEP VALLEY FARM INC, FIGHT BAC - DRUG FACILITY REGISTRATION, WARNING TLRS, PROD LISTING; EMPACK - LIQUIDATED DAMAGES RECS, ETC
2012-7325	10/11/2012 11/08/2012	FDA/OC/OES/DFOI/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	CARDINAL HEALTH 414 LLC, SEATTLE, WA; LAS VEGAS, NV, MEMPHIS, TN, ETC - EIRS, 483S
2012-7326	10/11/2012 11/15/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MCCASH, MARY	MICHAEL HAWOTTE, ALFACELL, CELEBREX, FLOMAX - RECS

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		FDA/OO/OFBA/OAGS/		
2012-7327	10/11/2012 11/08/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ONA SCANDURRA COUNTRY LIFE LLC	COUNTRY LIFE LLC, HAUPPAUGE, NY - EIRS, 483S 6/10 TO PRESENT
2012-7328	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR YA PING LEE CURTIN UNIV SCHOOL OF PHARMACY	ORAL PROTON PUMP INHIBITORS (PPI); OMEPRAZOLE, ESOMEPRAZOLE, ETC - AERS
2012-7329	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LYNAE CHANG Boscogen, Inc.	SYN TECH PHARM AND TECH, SINYING CITY, TAIWAN - INSP 5/12
2012-7330	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM G GAINER TOLIVER & GAINER	RANBAXY PHARMS - MINOCYCLINE LBLG CHANGE, CORR, APRVL RECS, ETC
2012-7331	10/11/2012 11/08/2012	ORA/ORM/ ORA/ORM/	DAVID P JORDAN THOMSON REUTERS	FOREIGN & DOMESTIC DRUG MFRS, REPACKERS, LABELERS, ETC INSPS 1/11 TO 12/11
2012-7332	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	GILLET #410314, TONY	IBOGAINE - RECS; STRANGE LOOKING MEAT SERVED BY GOVERNMENT EMPLOYEES - TESTING RECS
2012-7333	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DUBECK B00004, ROBERT	XANAX, ZOLOFT, SLEEP AIDS, ETC - SLEEP DRIVING RECS
2012-7334	10/11/2012 11/08/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	ANGIODYNAMICS, QUEENSBURY, NY - 483 7/12 TO 9/12
2012-7335	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROYA BORAZJANI COOPER VISION, INC	DELEFILCON A SOFT CONTACT LENS K113168
2012-7336	10/11/2012 11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROYA BORAZJANI COOPER VISION, INC	BAUSCH & LOMB - MESOFILCON A CONTACT LENS K113703

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2012-7337	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE AND PERINDOPRIL - AERS 7/21/12 TO PRESENT
2012-7338	10/11/2012 11/08/2012	OM/OMP/DODM/	MARY B SZALKOWSKI PRISMA CORP	NEUROPHARMACOLOGIC DRUGS A/C - TRANS 9/14/71
2012-7339	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	EISAI INC - DECITABINE INJ OGD BIOEQV REQUIREMENTS
2012-7340	10/11/2012 11/08/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	CELGENE - AZACITIDINE INJECTABLE SUSPENSION - BIEQV RECS
2012-7341	10/12/2012 11/09/2012	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2012-N-0378
2012-7342	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5105
2012-7343	10/12/2012 11/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN HARLOE JD PHD FREESE & GOSS, PLLC	OBSTETRICS & GYNECOLOGY MEDICAL DVCS A/C - RECS 9/8/11
2012-7344	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-6121
2012-7345	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5361
2012-7346	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5576
2012-7347	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-2862
2012-7348	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5996
2012-7349	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2011-7845
2012-7350	10/12/2012	FDA/OGROP/ORACE-FO/BLT-		GLAXOSMITHKLINE INC 8/9/12; EXPERIMENTAL

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	11/09/2012	DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SCHARBERG, DAVID L	PATHOLOGY LABS 8/14/12; TRS LABS INC 7/6/12, ETC - 483S 6/12 TO 8/12
2012-7351	10/12/2012 11/09/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5751
2012-7352	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-2638
2012-7353	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3213
2012-7354	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-5728
2012-7355	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-2920
2012-7356	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3057
2012-7357	10/12/2012 11/09/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	PAUL W TRIPP LINCARE INC	FLEXLIFE HEALTH INC (ZIN MEDICAL INC), OH - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-7358	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3296

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2012-7359	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	2012-3494
2012-7360	10/12/2012 11/09/2012	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/	BOOT, KEVIN	EMBRIA HEALTH SCIENCES LLC, ANKENY, IA - EIR 7/24/12
2012-7361	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 9/17-21/12
2012-7362	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 9/17-21/12
2012-7363	10/12/2012 11/09/2012	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	FOI Services, Inc.	PFIZER - VISINE PURE TEARS APRVL, CLNCL TRIAL, EFFICACY 2005
2012-7364	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 9/24-28/12
2012-7365	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 9/24-28/12
2012-7366	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 9/24-28/12
2012-7367	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 9/17-21/12
2012-7368	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 9/10-14/12
2012-7369	10/12/2012 11/09/2012	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	S. TIRUVENDRA RA CHEM PHARMA LTD	RA CHEM PHARMA LTD, ANDHRA PRADESH, INDIA - EIR 3/26/12 TO 4/3/12
2012-7370	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 9/24-28/12
2012-7371	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDID INC	CLOSED FOI REQUESTS 9/24-28/12
2012-7372	10/12/2012 11/09/2012	CVM/OC/DO/	THOMAS E. SOULE EDELMAN COMBS LATTURNER	CANADIAN BROADCASTING CORP INVESTIGATION OF IMPORTED CHICKEN JERKY USED AS PET FOOD

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		OC/OEXA/OPA/	ET AL	
2012-7373	10/12/2012 11/09/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	mahlaqa patel PATEL, MAHLAQA	NDA 017871 - SBA
2012-7374	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 9/24-28/12
2012-7375	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 9/24-28/12
2012-7376	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 9/24-28/12
2012-7377	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 10/1-5/12
2012-7378	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOI REQUESTS 10/1-5/12
2012-7379	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 10/1-5/12
2012-7380	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 10/1-5/12
2012-7381	10/12/2012 11/09/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 10/1-5/12
2012-7382	10/12/2012 11/09/2012	FDA/OMPT/CDRH/OCER/DFOI/	AYAMI MARUYAMA CANON INC	BARCO - MAMMO TOMOSYNTHESIS K103792; CORONIS FUSION 10MP K093197; EIZO - REDIFORCE RX840-MG K093197
2012-7383	10/15/2012 11/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Laura Jacques Jacques, Laura A	INFLUENZA VACCINE - VAERS
2012-7384	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ ORA/ ORA/	Andrew Pollack NEW YORK TIMES COMPANY	NEW ENGLAND COMPOUNDING COMPANY - MEETING MINUTES, 483, REPORTS

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2012-7385	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	David Hwang Mid-Link International Inc	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD - 483 (4/9/2012 to 4/12/2012)
2012-7386	10/15/2012 11/13/2012	OM/OMP/DODM/	John Connell John Connell	PETITIONS RE ARENA PHARM LORCASERIN, QNEXA
2012-7387	10/15/2012 11/13/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	David O'Connor PRACS INSTITUTE, LTD.	BA RESEARCH, HOUSTON, TX - EIRS (01/01/2005 - 12/31/2005)
2012-7388	10/15/2012 11/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sajjan Aryal ACCUCAPS INDUSTRIES LTD	IWAKI SEIYAKU CO LTD, KAKEGAWA CITY, JAPAN - EIR 10/08/2010
2012-7389	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/	MOI, Inc.	RFQ 1103834-SOL-2012 - ARBEE ASSOCIATES, INC. PROPOSAL
2012-7390	10/15/2012 11/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Grant Benten Films	ZYPREXA, RISPERDAL - ISR
2012-7391	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Medinnovo LLC	K081147
2012-7392	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Scott Ki Idaho Business Review	IBX, CARDIOGRIP, ZONA PLUS, ZONA RX - 510K
2012-7393	10/15/2012 11/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Weaver THE WALL STREET JOURNAL	CANADA DRUGS, CANADADRUGS.COM - FDA CORR RE 9/21/12 WARNING LETTER ETC
2012-7394	10/15/2012 11/13/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Alka Chandna PETA	TRIPLE F FARMS, SAYRE, PA - EMAILS, LETTERS, REPORTS, ETC
2012-7395	10/15/2012 11/13/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Bob Burns Talenti Gelato	JIMBO'S JUMBOS, INC, EDENTON, NC - EIRS (10/01/2009 - 10/11/2012)
2012-7396	10/15/2012 11/13/2012	FDA/OF/CFSAN/OCD/EOS/	Silvia Volkmann Orion Engineered Carbons GmbH	FAP 5B4464
2012-7397	10/15/2012 11/13/2012	FDA/OF/CFSAN/OCD/EOS/	Steve Barwick Barwick, Steve	SILVER CONTAINING DIETARY SUPPLEMENTS - RECS RE ABSORBING CERTAIN DRUGS
2012-7398	10/15/2012	FDA/OGROP/ORA/SE-FO/FLA-		ALMASED - RESPONSE TO 01/18/12 WARNING LETTER

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	11/13/2012	DO/FLA-CB/	Schraven, John	
2012-7399	10/15/2012 11/13/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Paula Eichman APTALIS PHARMATECH INC	NATIONAL VITAMIN, CASA GRANDE, AZ - EIRS LAST TWO YEARS
2012-7400	10/15/2012 11/13/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Amanda E. De Vito, Couch White LLP Couch White LLP	SICAP INDUSTRIES, LLC, ALBANY, NY; GSC PRODUCTS LLC, ALBANY, NY; WAYNE PERRY - RECS 01/01/03 TO 10/11/12
2012-7401	10/15/2012 11/13/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/OCI/ ORA/OCI/	ROBERT G BERNHOFT BERNHOF LAW FIRM SC	INDIVIDUAL RECS
2012-7402	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRANT WIGGER TRANSPHOTON CORP	APEX XL-4 K033001
2012-7403	10/15/2012 01/31/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LAWRENCE A BOHM ESQ BOHM LAW GROUP	INDIVIDUAL RECS
2012-7404	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT E COLLIER II COLLIER & ASSOCIATES LAW OFCS	TEVA PHARMACEUTICALS USA, TEVA NEUROSCIENCES INC - COPAXONE CMLNTS, RVWS, AERS, ETC
2012-7405	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARTIN R PRINCE MD PHD Weill Medical College of Cornell University	GADOLINIUM - ISRS 6055003, 6238473, ETC
2012-7406	10/15/2012 11/13/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOUGLAS P DOWD DOWD & DOWD PC	ABBOTT LABS - DEPAKOTE (DIVALPROEX SODIUM, VALPROIC ACID) AERS, WARNINGS, CO RESP, ETC
2012-7407	10/15/2012 11/13/2012	FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	AGROSUN INC - ENTRY #DV101281900 NOTICES OF FDA REFUSAL
2012-7408	10/15/2012 11/13/2012	ORA/OCI/ ORA/OCI/	Doe J	INDIVIDUAL RECS
2012-7409	10/15/2012	FDA/OC/OES/DFOI/	MEGHAN E RUESCH	USA FAR OCEAN GROUP INC - U-PROSTA NATURAL

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	11/13/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TRAUB LIEBERMAN STRAUS ET AL	SUPPORT FOR PROSTATE HEALTH CORR, WARNING LTRS, CMLPTS, ETC
2012-7410	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	2012-6833
2012-7411	10/15/2012 11/13/2012	FDA/OC/OES/DFOI/	JOHN H REED MD WORLD INSTITUTE FOR SCIENTIFIC EXPLORATION	FOI DAILY LOG FY 1966 TO FY 1999
2012-7412	10/15/2012 11/13/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	CRAIG ROUSH ROCKLINE INDUSTRIES	KLEEN TEST PRODUCTS CORP, PORT WASHINGTON, WI - EIR, 483, CORR 8/12
2012-7413	10/15/2012 11/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOUGLAS P DOWD DOWD & DOWD PC	HOFFMAN-LAROCHE/ROCHE LABS - ACCUTANE AERS, WARNINGS, CO RESP, ETC
2012-7414	10/15/2012 11/13/2012	FDA/OF/CFSAN/OCD/EOS/	HALEY, KALA	FREE RANGE, CAGE FREE ANIMAL PRODS - DEFINITIONS, VIOLATIONS, FALSE ADVERTISING, ETC
2012-7415	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	STUTE, HANK	CPT1200119
2012-7416	10/15/2012 12/06/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN RICHARSON Surveyor Capital	BAXTER HEALTHCARE CORP-BAXTER AG 1/21/10; BAXTER BIOSCIENCE 1/28/10; BAXTER MANUFACTURING SPA 9/1/09, ETC - 483S
2012-7417	10/15/2012 11/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	John Blewitt LIFECCELL CORPORATION	K080442
2012-7418	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bernita Vick MPR Associates, Inc.	K012769
2012-7419	10/16/2012 11/14/2012	FDA/OF/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 1103
2012-7420	10/16/2012 11/15/2012	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-	Richard R. Stephens Stephens, Richard R	TEST RESULTS

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		DO/DAL-CB/		
2012-7421	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lee, Ellese N	ONCASPAR - AERS
2012-7422	10/16/2012 11/14/2012	FDA/OGROP/ORA/ORO/DIOP/ THE NEW YORK TIMES		OASIS DATA
2012-7423	10/16/2012 11/14/2012	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	LYNN R WEBSTER, SALT LAKE CITY, UT - MOST RECENT 483
2012-7424	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathy Takeuchi, Pharm.D. HARBORVIEW MEDICAL CENTER	HYDROXUREA - AERS
2012-7425	10/16/2012 11/14/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Connie Romaine LSU Health Sciences Center in New Orlean	LSU HEALTH SCIENCES CENTER, NEW ORLEANS, LA - RESPONSE TO LETTER DATED 06/29/12
2012-7426	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KMGH-TV	PRADAXA - AERS
2012-7427	10/16/2012 11/14/2012	FDA/OF/CFSAN/OCD/EOS/	Bethany Walls INTERTEK	FCN 1167
2012-7428	10/16/2012 11/14/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	ACCURAY INC, SUNNYVALE, CA; MEDTRONIC ADVANCED ENERGY LLC, PALO, ALTO, CA; SKELETAL KINETICS LLC, CUPERTINO, CA, ETC - 483S 7/1-31/12
2012-7429	10/16/2012 11/14/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	WYETH PHARMACEUTICAL CO (PFIZER CONSUMER HEALTHCARE), GUAYAMA, PR; ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR; SURGICAL SPECIALTIES PUERTO RICO INC (ANGIOTECH PR INC), AGUADILLA, PR - 483S 7/1-31/12
2012-7430	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Huan Tran Next Orthosurgical, Inc.	K102694
2012-7431	10/16/2012	FDA/OC/OES/DFOI/	Sarah Freishtat	MEDIA FOIA REQUESTS LAST SIX MONTHS

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	11/14/2012		MEDILL SCHOOL OF JOURNALISM	
2012-7432	10/16/2012 11/14/2012	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	VIDCO INC, BEAVERTON, OR; KOREGON ENTERPRISES INC (NITE TRAIN'R), BEAVERTON, OR; ATOSSA GENETICS INC, SEATTLE, WA, ETC - 483S 7/1-31/12
2012-7433	10/16/2012 11/14/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Tracy Taylor Tracy Taylor	ROCHE CAROLINA, FLORENCE, SC - EIR, 483 03/01/2012 - 10/01/2012
2012-7434	10/16/2012 11/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER MANUFACTURING SPA, RIETI, ITALY - 483S 7/1-31/12
2012-7435	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	HISUN PHARMACEUTICAL HANGZHOU CO LTD, FUYANG CITY, CHINA; ALCHEM INTERNATIONAL LTD, BALLABGARH, FARIDABAD, HARYANA, INDIA; CENEXI LABORATORIES THISSEN SA, BRAINE L'ALLEUD, BELGIUM, ETC - 483S 7/1-31/12
2012-7436	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	TAIWAN KING STRONG CO LTD, TAICHUNG CITY, TAIWAN; XIANTAO RAYXIN MEDICAL PRODUCTS CO LTD, XIANTAO CITY, CHINA; VBM MEDIZINTECHNIK GMBH, SULZ AM NECKAR, GERMANY, ETC - 483S 7/1-31/12
2012-7437	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	BLOOMEX INTERNATIONAL INC, ELMWOOD PARK, NJ; INTEGRA LIFESCIENCES CORP, PLAINSBORO, NJ - 483S 7/1-31/12
2012-7438	10/16/2012 11/14/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	SUNBEAM PRODUCTS INC (JARDEN CONSUMER SOLUTIONS), WAYNESBORO, MS; SOURCE PRODUCTION & EQUIPMENT CO INC, ST ROSE, LA; KNU LLC, LELAND, MS - 483S 7/1-31/12
2012-7439	10/16/2012 11/14/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	GENZYME CORP, FRAMINGHAM, MA; TWINCRAFT INC, WINOSKI, VT; SPECIALTY MINERALS INC, ADAMS, MA, ETC - 483S 7/1-31/12
2012-7440	10/16/2012 11/14/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	CORE LABS LLC, ENGLEWOOD, CO - 483S 7/1-31/12
2012-7441	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	NATURAL ESSENTIALS INC, STREETSBORO, OH; AMYLLIN OHINO LLC, WEST CHESTER, OH; SCOTTCARE CORP, CLEVELAND, OH - 483S 7/1-31/12
2012-7442	10/16/2012 11/14/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	PRIMROSE CANDY CO, CHICAGO, IL; ABBOTT MOLECULAR, DES PLAINES, IL; HOSPIRA INC, LAKE FOREST, IL - 483S 7/1-31/12
2012-7443	10/16/2012 11/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEVIN M FITZERLAND LEWIS SAUL & ASSOCS	ORTHO PHARMACEUTICAL, CORP; ORTHO-MCNEIL PHARMACEUTICALS INC; PRICARA, ETC - LEVAQUIN AERS, TRANS, LTRS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/		
2012-7444	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	KEVIN M FITZGERALD LEWIS SAUL & ASSOCS	SCHERING-PLOUGH CORP; SCHERING CORP; MERCK & CO INC - AVELOX AERS, TRANS, LTRS; ETC
2012-7445	10/16/2012 11/14/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	BRISTOL MYERS SQUIBB CO, EAST SYRACUSE, NY; MOGEN INSTRUMENTS, BROOKLYN, NY; SMARTPILL CORP, BUFFALO, NY - 483 7/12
2012-7446	10/16/2012 11/14/2012	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	VIRGINIA BLOOD SERVICES, RICHMOND, VA - 483 7/12
2012-7447	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Justine Hager Biodel Inc.	NDA 018780
2012-7448	10/16/2012 11/14/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	BANNER PHARMACAPS INC, HIGH POINT, NC; NEWTON LABORATORIES INC, CONYERS, GA; CR BARD INC, COVINGTON, GA - 483 7/12
2012-7449	10/16/2012 11/14/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	POLYMER TECHNOLOGY SYS INC, INDIANAPOLIS, IN; AXIOBIONICS LLC, ANN ARBOR, MI - 483 7/12
2012-7450	10/16/2012 11/14/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	ATLANTIC PRO NUTRIENTS INC, ORLANDO, FL; DEXTRUM LABORATORIES INC, MIAMI, FL; ADVANCED RADIATION MEASUREMENT INC, FT PIERCE, FL - 483 7/12
2012-7451	10/16/2012 11/14/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	AUXILIUM PHARMA INC, HORSHAM , PA; PARTICLE SIZE TECHNOLOGY INC, QUAKERTOWN, PA; HERCON LABORATORIES CORP, EMIGSVILLE, PA - 483 7/12
2012-7452	10/16/2012 11/14/2012	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	MARCUS RESEARCH LAB INC, ST LOUIS, MO - 483 7/12
2012-7453	10/16/2012 11/14/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	HEALTH PLUS INC, CHINO, CA; LEVLAD LLC, CHATSWORTH, CA; BLAINE LABS INC, SANTA FE SPRINGS, CA - 483 7/12
2012-7454	10/16/2012 11/14/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	WISCONSIN PHARMACAL CO LLC, JACKSON, WI; KLEEN TEST PRODUCTS CORP, PORT WASHINGTON, WI; AJD LABORATORIES INC, PARK RAPIDS, MN - 483 7/12
2012-7455	10/16/2012 11/14/2012	ORA/ ORA/	JOHNATHAN RICKMAN FDA NEWS	TAKEDA PHARMACEUTICAL CO LTD, HIKARI, JAPAN - 483 7/12

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2012-7456	10/16/2012 11/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/10-14/12
2012-7457	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sue Corbett THE RESEARCH INVESTMENT, INC.	GUIDANCE CONJUGATED ESTROGEN TABLETS - IN VIVO BIOEQUIVALENCE, IN VITRO DRUG RELEASE
2012-7458	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Bonifield CNN	EPIDURAL INJECTION OF NECC PRODUCT - DATE OF EXPOSURE, NAME AND LOCATION OF FACILITY; TRANSPLANT PATIENTS - DATES OF EXPOSURE, NAME AND LOCATION OF FACILITIES
2012-7459	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K082298
2012-7460	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21520 S 012
2012-7461	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Justine Hager Biodel Inc.	NDA 020928
2012-7462	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Justine Hager Biodel Inc.	NDA 018780
2012-7463	10/16/2012 11/14/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Susan Searles IKARIA INC	AVANTOR MATERIALS, CENTER VALLEY, PA - EIR (01/03/2011 - 10/16/2012)
2012-7464	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF	K963226, K931386, K915774

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			MEDICINE	
2012-7465	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K831949, K923367, K926138
2012-7466	10/16/2012 11/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M. ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K083191
2012-7467	10/16/2012 11/14/2012	ORA/ ORA/	BRIAN HARTMAN ABC NEWS	SUNLAND INC - SALMONELLA OUTBREAK 2007 TO PRESENT
2012-7468	10/16/2012 11/14/2012	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2012-7469	10/16/2012 11/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NICOLAS 635504, ALBERT	PFIZER - LYRICA AER
2012-7470	10/16/2012 11/14/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/1-5/12
2012-7471	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	Paul Knoepfler UNIVERSITY OF CALIFORNIA, DAVIS	CELLTEX, SUGARLAND, TX - WARNING LETTER
2012-7472	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	Mark Jackson ARCADIS	FCN 1096
2012-7473	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Johnathan Rickman FDA NEWS	HOLOPACK, GERMANY - 483 2/24/2012
2012-7474	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Imran Karim	K101382

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2012-7475	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	Wheeler, Lisa P	REPORT BY FDA TO HHS RE LABELING OF INFANT FORMULA 1981
2012-7476	10/17/2012 11/15/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drew Barlow Vertex Pharmaceuticals Incorporated	VERTEX PHARM INC. - QAP; EIR 12/21/11-01/13/12
2012-7477	10/17/2012 11/15/2012	ORA/ ORA/	James Andrews FOOD SAFETY NEWS	SUNLAND, INC - INSPECTION RECS 03/01/2009 - 10/16/2012
2012-7478	10/17/2012 11/15/2012	ORA/ ORA/	Cheryl Bernard Bernard, Cheryl	SUNLAND INC - EIR, 483, RESPONSES 08/01/2009 - 10/16/2012
2012-7479	10/17/2012 12/20/2012	FDA/OF/CFSAN/OCD/EOS/	Mark Jackson ARCADIS	FCN 1021
2012-7480	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	Mark Jackson ARCADIS	FCN 1020
2012-7481	10/17/2012 11/15/2012	FDA/OO/OFBA/OAGS/	Strategi Consulting	HHSF223201210029I - PROPOSAL, AWARDED CONTRACT, MODIFICATIONS
2012-7482	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gary Pekoe, Phd., or Kelley Creamer, Regulatory Affairs Mngr PluroGen Therapeutics, Inc.	PLUROGEL 45-5 CONCENTRATE CLEANSING PRODUCT - DEVICE CORR
2012-7483	10/17/2012 11/15/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	LEERINK SWANN & CO	ALERE, SAN DIEGO, CA - RESPONSE TO 483 7/17/12
2012-7484	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rob Disselkamp Rob Disselkamp	RISPERIDONE - AERS
2012-7485	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rob Disselkamp Rob Disselkamp	DEPAKOTE - AERS
2012-7486	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2009-8268
2012-7487	10/17/2012	FDA/OC/OES/DFOI/	AMY KINCANON	2010-2408

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	11/15/2012		LEXIS NEXIS COURTLINK INC	
2012-7488	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	AMY KINCANON LEXIS NEXIS COURTLINK INC	2010-8869
2012-7489	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155879 - CAERS ADDITIONAL RECS
2012-7490	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155912 - CAERS ADDITIONAL RECS
2012-7491	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155912 - CAERS ADDITIONAL RECS
2012-7492	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	155879 - CAERS ADDITIONAL RECS
2012-7493	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MARY BETH HENDERSON RCRI	THERMOCHEM-HT SYS - K993330
2012-7494	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/	HENRY GLUCKSTERN HENRY GLUCK ATTY	SABIN TRIVALENT ORAL POLIO VACCINE - FOI REQUESTS 1/00 TO PRESENT
2012-7495	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ CVM/OCD/	THOMAS D GOODRICH PHD PHARMAQ	SHANGHAI ZHONGXI SUNVE PHARMACEUTICAL CO LTD, SHANGHAI, CHINA - EIRS, 483S MOST RECENT
2012-7496	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	JAY S TRIVEDI PATRIN PHARMA INC	MALLINCKRODT - METHYLPHENIDATE ORAL SOL NDA 21-419 10 MG, 5 ML 12/19/O2; TRISH PHARMA - METHYLPHENIDATE ORAL SOL ANDA 91-601 5 MG, 5 ML 7/23/10
2012-7497	10/17/2012 11/15/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LIA OBATA DOWD DOWD & DOWD PC	MERCK SHARP & DOHME CORP - FOSAMAX AERS, NDA, RESP
2012-7498	10/17/2012	FDA/OMPT/CDER/ORP/DIDP/	RITA BECHARA	AMARIN PHARMA INC - VASCEPA NDA 202-057 PRVL PKG 7/26/12

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	11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ACASTI PHARMA INC	
2012-7499	10/17/2012 11/15/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHESTER C STETFELT JR CHESTER C STETFELT JR OFC	PREMPRO, PROVERA - RECS
2012-7500	10/17/2012 11/15/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	PARADIGM QUICK-SET INFUSION SETS K011071 - EIRS, CMLPTS, ETC
2012-7501	10/17/2012 11/15/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	PATI WALLER MARLER CLARK ATTYS	DOCTORS MEDICAL CENTER, MODESTO, CA - SALMONELLA IN INFANT FORMULA COMM, LAB RESULTS, RPTS, ETC 4/12, 5/12
2012-7502	10/17/2012 11/15/2012	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	MONTY DUCK BEF FOODS INC	BEF FOODS INC, SULPHUR SPRINGS, TX - LAB RESULTS 9/11/12
2012-7503	10/17/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ ORA/OE/ ORA/OE/ ORA/ORO/DFS/ ORA/ORO/DFS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA-	CARRIE LUBINSKI GORDON & REES LLP	MANGOES OUTBREAK OF SALMONELLA - SPLS, LAB NOTEBOOKS, W/S, ETC 2012

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		DO/SEA-CB/ FDA/OGROP/ORR/SE-FO/NOL- DO/NOL-CB/		
2012-7504	10/17/2012 11/15/2012	ORA/ ORA/	MARY CLARE JALONICK ASSOCIATED PRESS	SUNLAND INC - OUTBREAK OF SALMONELLA IN PEANUT BUTTER 483S 2009, 2010, 9/12
2012-7505	10/17/2012 11/15/2012	OC/COS/OES/ OC/COS/OES/	VANESSA, STARKS	HHS MANDATED INVESTIGATION OF THE OC OR OO OFFICE OF MANAGEMENT RPT INCLUDING ANY RELATED RECS FOR OFFICE OF MANAGEMENT & OFFICE OF MANAGEMENT PROGRAMS
2012-7506	10/17/2012 11/15/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Diane Hawkins Hawkins, Diane	INDIVIDUAL RECS
2012-7507	10/17/2012 11/15/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K002612
2012-7508	10/17/2012 11/15/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K001143
2012-7509	10/17/2012 11/15/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	LESLEY S ZORK JACK H OLENDER LAW OFCS	INDIVIDUAL RECS
2012-7510	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Allison Komiyama PaxMed International	K052168
2012-7511	10/18/2012 11/16/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ ORA/ ORA/ FDA/OC/OES/ OC/COS/OL/ OC/OCC/ OC/OL/	Matthew Stone Cohen, Placitella & Roth	NEW ENGLAND COMPOUNDING CENTER - INVESTIGATION RECS
2012-7512	10/18/2012	FDA/OMPT/CDER/ERP/DIDP/	Glen Spielmans	SYMBYAX - REVIEW RECS

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	11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Metropolitan State University - Psyc Dpt	
2012-7513	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21455 S7
2012-7514	10/18/2012 11/16/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	RBC CAPITAL MARKETS	ST JUDE MEDICAL, SOMAR, CA - 483 09/01/2012 - 11/30/2012
2012-7515	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA50495 - TOXICOLOGY DATA
2012-7516	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	HemoSonics LLC	K083842
2012-7517	10/18/2012 11/16/2012	FDA/OF/CFSAN/OCD/EOS/	Aaron Kochman Lauren AgriSystems	ALLOWABLE CARBON BLACK LOADING 21 CFR 177.2600
2012-7518	10/18/2012 11/16/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL, SYLMAR, CA - CORR RE ONGOING INSPECTION
2012-7519	10/18/2012 11/16/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA202236
2012-7520	10/18/2012 11/16/2012	FDA/OC/OES/DFOI/	WINGARD, MICHELLE	FOIA REQUESTS 8/1/12 TO 9/1/12
2012-7521	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HERAEUS KULZER LLC - GLUMA DESENSTITZER POWER GEL K093575
2012-7522	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	COLGATE-PALMOLIVE CO - COLGATE DESENSTIZING DENTAL CREAM K103461
2012-7523	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HOENIX DENTAL INC - SUPER SEAL TOOTH DESENSITZER K120109
2012-7524	10/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN	JENERIC/PENTRON INC - QUELL DESENSTIZER K010957

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	11/16/2012	FDA/OC/OES/DFOI/	HARVEST CONSULTING CORP	
2012-7525	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	PIA MALBRAN CBS MIAMI	DETLOGIX ANNULOPLASTY RING - K083191
2012-7526	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	SANDRA BROWN REICHERT TECHNOLOGIES	REICHERT INC - POD PAC 20M CORNEAL PACHYETER SYS K030610
2012-7527	10/18/2012 11/16/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	BAXTER PHARMACEUTICAL SOLUTIONS	BAXTER PHARMACEUTICAL SOLUTIONS, LLC, BLOOMINGTON, IN - EIR 01/03/2011 - 10/17/2012
2012-7528	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	Annette Nelson CooperVision, Inc.	K100456
2012-7529	10/18/2012 11/16/2012	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MATHEW A ZEPNICK EDELSTEINS FAEGENBURG & BROWN LLP	TRANS1 AXIAL LIF 2L ANTERIOR SPINAL FIXATION - INVESTIGATIVE RECS 7/8/10
2012-7530	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	Annette Nelson CooperVision, Inc.	K100349
2012-7531	10/18/2012 11/16/2012	FDA/OMPT/CTP/OD/	THE ASSOCIATED PRESS	CTP - NUMBER OF EMPLOYEES WORKING ON REVIEW OF SUBSTANTIAL EQUIVALENCE APPLICATIONS
2012-7532	10/18/2012 11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN E HALL MEDICINE HALL	PHILIPS HEARTSTREAM - PHILIPS HEARTSTART HOME DEFIBRILLATOR K040904, K020715, K003565 CLEARANCE LTR & PROD INSERT
2012-7533	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATHERNE, MICHAEL MARK	CIPRO (CIPROFLOXACIN) - AERS
2012-7534	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ASHLEY E BASS COVINGTON & BURLING LLP	BUDEPRION XL 300 MG (WELLBUTRIN XL 300 MG) - MEETINGS, COMM, SUBMISSIONS, ETC
2012-7535	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS P VALET RHEINGOLD, VALET, ET AL	FDA SCIENCE BACKGROUND PAPER: ACUTE PHOSPHATE NEPHROPATHY & RENAL FAILURE ASSOCIATED WITH THE USE OF ORAL SODIUM PHOSPHATE BOWEL CLEANSING PRODS; FDA SAFETY INFORMATION/WARNING REGARDING FLEET PHOSPHO-SODA & FLEET ACCU-PREP 5/5/06 (CERTIFIED)
2012-7536	10/18/2012 11/16/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SANJAY H SHARMA HETERO USA INC	GLUCOTROL XL (GLIPIZIDE ER TABS) 2.5 MG, 10 MG - CHEMISTRY RVWS, SBA, BIOEQV

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2012-7537	10/18/2012 11/16/2012	FDA/OF/CFSAN/OCDE/EOS/	JONES 06-A-0604, VERNON	WHAT ANIMAL IS THE SURGE OF SOYA LECITHIM ARTIFICIAL COLORS ACID, ETC
2012-7538	10/18/2012 11/16/2012	FDA/OF/CFSAN/OCDE/EOS/	LISA Y LEFFERTS CENTER FOR SCIENCE IN PUBLIC INTEREST	SEARLE LABS - TWO YR TOXICITY STUDY IN THE RAT, 104 WEEK 2 GENERATION IN UTERO STUDY IN RAT, 115 WEEK ORAL TUMORIGENICITY STUDY IN THE RAT CARCINOGENICITY STUDIES ON ASPARTAME
2012-7539	10/18/2012 11/16/2012	ORA/ ORA/	MARTINA BERNSTEIN PETA FOUNDATION	BOVINE SPONGIFORM ENCEPHALOPATHY - MEMOS, RPTS, EVALUATIONS, ETC
2012-7540	10/18/2012 11/16/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MELANIE COURTOT UNIV OF BRITISH COLUMBIA	ADVERSE EVENTS FOLLOWING INFLUENZA A (H1N1) MONOVALENT VACCINES 10/09 TO 1/31/10
2012-7541	10/18/2012 11/16/2012	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Doe J	DOLE CORP - SPINACH RECS
2012-7542	10/18/2012 11/16/2012	FDA/OC/OES/DFOI/	JEFF STACHEWICZ FOIA GROUP INC	MC252 WELL - IDENTIFYING COMPOSITON OF OIL, QUANTITY OF OIL, FATE & TRANSPORT, ETC
2012-7543	10/19/2012 11/19/2012	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2012-P-0904
2012-7544	10/19/2012 11/19/2012	OC/OM/OMP/DDM/	GABRIEL SHERMAN Hyman Phelps and McNamara PC	DKT FDA-2012-P-0939
2012-7545	10/19/2012 11/19/2012	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	AnnMarie Beattie Harmonized Customs Brokers, Inc	ENTRY G76-0129053-7 - LAB RESULTS
2012-7546	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ofek Levin Via Surgical Ltd	K091900
2012-7547	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ofek Levin Via Surgical Ltd	K093845
2012-7548	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Huan Tran Next Orthosurgical, Inc.	K110125
2012-7549	10/19/2012 11/19/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Molly Moore Leader, Bulso & Nolan	NEW ENGLAND COMPOUNDING PHARMACY - INVESTIGATIVE RECS, CORR, MEMOS, ETC.

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2012-7550	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	MERCK , WEST POINT, PA- EIRs, 483s, CORR (01/01/2009-12/31/2010)
2012-7551	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Holli Baker Ridley, McGreevy & Winocur P.C.	REACTION NUTRITION, CARNEGIE, PA - 483, RESPONSE 4/22/2010 - 10/17/2012
2012-7552	10/19/2012 11/19/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT LISTING FOR ALTRIA, PHILIP MORRIS, SMOKELESS TOBACCO
2012-7553	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K112860
2012-7554	10/19/2012 11/19/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CORR BETWEEN CTP AND INDUSTRY RE CAPSULES IN CIGARETTES
2012-7555	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K103254
2012-7556	10/19/2012 11/19/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	LIST OF PRODUCTS - ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, SMOKELESS TOBACCO LLC ETC
2012-7557	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Allison Komiyama PaxMed International	K083770
2012-7558	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ofek Levin Via Surgical Ltd	K092483
2012-7559	10/19/2012 11/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexandra Perreiter Sharp Memorial Hospital	RIVAROXABAN - AERS
2012-7560	10/19/2012 11/19/2012	FDA/OF/CFSAN/OCD/EOS/	Michael Keegan WaterCensus	BOTTLED WATER COMPANIES - TESTING DATA RESULTS SUBMITTED TO FDA UNDER CURRENT REGULATIONS (01/01/2011 - 12/31/2011)
2012-7561	10/19/2012 11/19/2012	FDA/OO/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	LIST OF MEDICAL OFFICERS AT FDA

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2012-7562	10/19/2012 11/19/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	UNITED I INTERNATIONAL LABORATORIES LLC, CARROLLTON, TX; HOSPIRA INC, AUSTIN, TX; MEDICA RENTS CO LTD, FORT WORTH, TX - 483 8/12
2012-7563	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	BARTON CAREY MEDICAL PRODUCTS INC, MAUMEE, OH; KDB INC, CRESENT SPRINGS, KY - 483 8/12
2012-7564	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BLISTEX INC, OAK BROOK, IL; PHOENIX INSTRUMENTS INC, NAPERVILLE, IL - 483 8/12
2012-7565	10/19/2012 11/19/2012	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	ALLO SOURCE INC, CENTENNIAL, CO; MOOG MEDICAL DEVICES GROUP, SALT LAKE CITY, UT - 8/12
2012-7566	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	CARACO PHARMACEUTICAL LABORATORIES LTD, DETROIT, MI; PHARMACIA & UPJOHN LLC, KALAMAZOO, MI - 483 8/12
2012-7567	10/19/2012 11/19/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	MDR FITNESS CORP, SUNRISE, FL; HILL DERMATEUTICALS INC, SANFORD, FL; NEPHRON PHARMACEUTICALS CORP, ORLANDO, FL - 483 8/12
2012-7568	10/19/2012 11/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	TAKEDA PHARMACEUTICAL CO LTD, OSAKA, JAPAN; UNITED BIOMEDICAL INC, HSIN CHU HSIEN, TAIWAN; CONCORD BIOTECH LTD, AHMEDABAD, GUHURAT STATE, INDIA - 483 8/12
2012-7569	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	SUZHOU HUANQIU ACUPUNCTURE MEDICAL APPLIANCE CO LTD, SUZHIU CITY, CHINA; TONICA ELEKTRONIK AS FARUM, DENMARK; RICHWAY NF, SEOUL, KR - 483 8/12
2012-7570	10/19/2012 11/19/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	KC PHARMACEUTICALS INC, POMONA, CA; VITAMINERALS INC, GLENDALE, CA; BEAUTY HEALTH & SCIENCE INNOVATIONS INC, PICO RIVERA, CA - 483 8/12
2012-7571	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	INCONTROL MEDICAL LLC, BROOKFIELD, WI - 483 8/12
2012-7572	10/19/2012 11/19/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JHONATHAN RICKMAN FDA NEWS	VERTEX PHARMACEUTICALS INC, CAMBRIDGE, MA; ALEXION PHARMACEUTICALS INC, SMITHFIELD, RI; TENDER CORP, LITTLETON, NH - 483 8/12
2012-7573	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	ELITE LABORATORIES INC; SUITE K VALUE ADDED SERVICES LLC, EDISON, NJ; WEST-WARD PHARMACEUTICAL CORP, EATONTOWN, NJ - 483 8/12
2012-7574	10/19/2012 11/19/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	ZION ORGANICS INC, SAINT ALBANS, NY; SAFETEC OF AMERICA INC, BUFFALO, NY; COLUMBIA PRESBYTERIAN MEDICAL CTR, NEW YORK, NY - 483 8/12
2012-7575	10/19/2012	FDA/OGROP/ORA/CE-FO/PHI-	JOHNATHAN RICKMAN	GUARDIAN ANGEL PRODUCTS INC, HUNTINGDON VALLEY,

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	11/19/2012	DO/PHI-CB/	FDA NEWS	PA; SPRING HEALTH PRODUCTS INC, NORRISTOWN, PA; GLYCADIA INC, PHILADELPHIA, PA - 483 8/12
2012-7576	10/19/2012 11/19/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	TEXCHEM CHEMICAL CO, SACRAMENTO, CA; GENENTECH INC, SOUTH SAN FRANCISCO, CA; CONSESNSUS ORTHOPEDICS INC, EL DORADO HILLS, CA - 483 8/12
2012-7577	10/19/2012 11/19/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	CANGENE BIOPHARMA INC, BALTIMORE, MD; HAWKNAD MANUFACTURING INDUSTRIES INC, ALEXANDRIA, VA; IBA MOLECULAR NORTH AMERICA INC, MORGANTOWN, WV - 483 8/12
2012-7578	10/19/2012 11/19/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	GILES CHEMICAL, WAYNESVILLE, NC; CAROLON CO, RURAL HALL, NC, PERKIN ELMER HEALTH SCIENCES, SC - 483 8/12
2012-7579	10/19/2012 11/19/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	PETNET SOLUTIONS INC, SPOKANE, WA; PARKS MEDICAL ELECTRONICS INC, ALOHA, OR; ELECTRODE STORE INC, BUCKLEY, WA - 483 8/12
2012-7580	10/19/2012 11/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OM/OMP/DODM/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	OBSTETRICS AND GYNECOLOGY MEDICAL DVCS A/C - PELVIC MESH RECS , CORR 9/8/11
2012-7581	10/19/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHN P. HARLOE, JD, PhD FREESE & GOSS, PLLC	PELVIC MESH STUDY PROTOCOLS, ENFORCEMENT ACTIONS, CORR, ETC
2012-7582	10/21/2012 11/19/2012	FDA/OF/CFSAN/OCD/EOS/	Bill Lesko Arizona Chemical, LLC	TETATOLOGICAL EVALUATION STUDIES OF FDA 71-28 (NATURALLY OCCURING SUBSTANCE FROM PINE TREES)
2012-7583	10/21/2012 11/19/2012	FDA/OF/CFSAN/OCD/EOS/	Anna Edney BLOOMBERG NEWS	CAERS REPORTS - 01/01/2004 - 10/19/2012
2012-7584	10/21/2012 11/19/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Nicki Steel Nicki Steel	KELLOGG'S MORNING STAR FARMS - CORR RE LABELING INFORMATION FOR SERVING SIZE OF MEAL STARTER CRUMBLES
2012-7585	10/21/2012 11/19/2012	CVM/OCD/	JoNel Aleccia MSNBC.COM	YANTAI ASKA FOODS CO LTD, SHANDONG, CHINA - EIR 03/28/2012 - 03/30/2012
2012-7586	10/21/2012 11/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	CORIN USA	K922841
2012-7587	10/21/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-6780 REQUEST LETTER

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	11/19/2012		MERCK & CO., INC.	
2012-7588	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6487
2012-7589	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6663
2012-7590	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6271
2012-7591	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6270
2012-7592	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6118
2012-7593	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5604
2012-7594	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3211
2012-7595	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-3929
2012-7596	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6641 REQUEST LETTER
2012-7597	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6956 REQUEST LETTER
2012-7598	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6625 REQUEST LETTER
2012-7599	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6685 REQUEST LETTER
2012-7600	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6604 REQUEST LETTER
2012-7601	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6824 REQUEST LETTER
2012-7602	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6876 REQUEST LETTER
2012-7603	10/21/2012 11/19/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6891 REQUEST LETTER

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2012-7604	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K926344
2012-7605	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K881604, K760152, K771046, ETC
2012-7606	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K880660, K863492, K905289, ETC
2012-7607	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K991764, K930428, K952684, ETC
2012-7608	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K893626
2012-7609	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K922164, K914350, K913641, ETC
2012-7610	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K942146, K885054, K953255, ETC
2012-7611	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRENT M ARDAUGH NORTHWESTERN UNIV FEINBERG SCHOOL OF MEDICINE	K003358, K961160, K010726
2012-7612	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIE RUFRANO-WILSON CARDINAL HEALTH	CARDINAL HEALTH INC - LEADXER LABELER CODE 37205
2012-7613	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIE RUFANO-WILSON CARDINAL HEALTH	CARDINALHEALTH INC - THE MEDICINE SHOPPE LABELER CODE 49614

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-7614	10/22/2012 11/20/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DOUGHLAS N BLUE II ZETETIC INC	SYNTHES SMP SA DECV CTO MEDICAL N 49, SATELITE NAUCALPAN, MEXICO - SYNTHES MEDICAL INSTRUMENTS ENTRY T9400573893
2012-7615	10/22/2012 11/20/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	TOILETRIES (COCOA LOTION, ALOE LOTION, ESSENTIAL MOISTURIZER) ENTRY 10908618795
2012-7616	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN BELL BOSTON SCIENTIFIC	A TABLE OF ALL MDRS IN MAUDE - MDR RPT KEY & THE PATIENT PROBLEM CODE
2012-7617	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	CHANGES TO OR MODIFICATIONS OF FORM FDA 3429 GENERAL DVC CLASSIFICATION QUESTIONNAIRE - MEMO 5/12 TO PRESENT
2012-7618	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA R MORGAN ALERE DAN DIEGO INC	ROCHE DIAGNOSTICS - COAGUCHEK XS PLUS SYS APPL CLIA WAIVER
2012-7619	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANCIS HY GREEN MD UNIV OF CALGARY/DEPT OF PATHOLOGY & LABORATORY MEDICINE	ALLIANCE PHARMS - IMAGENT GI PI
2012-7620	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	ELISA TOSTADO STRYKER SUSTAINABILITY SOLUTIONS	HARMONIC ACE - 5MM DIAMETER SHEARS 23 K120729; HARMONIC ACE - LAPAROSCOPIC 5MM DIAMETER SHEARS 36 CM LENTH ADAPTIVE TISSUE TECHNOLOGY K121550
2012-7621	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	LINZESS (LINACLOTIDE) CAPS NDA 202-811 APRVL RECS 8/30/12
2012-7622	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIA RUFRANO-WILSON CARDINAL HEALTH	KINRAY INC - LABELER CODE 63777
2012-7623	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GEORGE SHAMSOUN METHAPHARM INC	PRE-PEN - NDA 05-114 APRVL RECS, REVIEWER'S NOTES
2012-7624	10/22/2012	FDA/OGROP/ORA/CE-FO/NWJ-		CAMPBELL CO, CAMDEM, NJ - RECS, RESULTS 2008 TO

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	12/03/2012	DO/NWJ-CB/	GISSENDAMMER, ROBIN	2012
2012-7625	10/22/2012 11/20/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JAMES A LOCHRIDGE JR PREIS & ROY	CREATIVE COMPOUNDS LLC - RPTS, TEST RESULTS, PHOTOGRAPHS, ETC 1/10, 2/10 (CERTIFIED)
2012-7626	10/22/2012 11/20/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	STACI M TROLIAN BIOMET INC	DR MARK PHILLIPS FRIGGLE - WARNING LTR CORR, RECS
2012-7627	10/22/2012 11/20/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/	NICKERSON HILL ALLERGAN MEDICAL	ANULEX TECHNOLOGIES - INSP 8/23/10-9/22/10, WARNING LTR RESP 3/3/11, FDA RESP TO K111261 6/20/11, ETC
2012-7628	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINA M MIRACLE HILL-ROM	HILL-ROM INC - K001019, K001242, K003335, ETC
2012-7629	10/22/2012 11/20/2012	FDA/OF/CFSAN/OCD/EOS/	AHRENS, AMY	GENETICALLY MODIFIED CORN - BT BACTERIUM RECS
2012-7630	10/22/2012 11/20/2012	CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEVE D MATTERI CONTEMPORARY PRODUCTS INC	SICHUAN LONG MARCH PHARMACEUTICAL CO LTD, SICHUAN, CHINA - EIRS 9/9-15/09. 9/19-22/11
2012-7631	10/22/2012 11/20/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS M BLUE II ZETETIC INC	MARS CHOCOLATE PRODS ENTRY #30070573942 - RECS
2012-7632	10/22/2012 11/20/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	MARS CHOCOLATE PRODS ENTRY #30070573959 - RECS
2012-7633	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES INC	MINNTECH CORP - RAPICIDE OPA-28 K120306
2012-7634	10/22/2012 11/20/2012	OC/OCC/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	SUPERNUS NDA DISCUSSION - TRANS 10/3/12

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2012-7635	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NICOLAS 635504, ALBERT	PFIZER, PARKER-DAVIS - LYRICA AERS, CLNCL STUDIES
2012-7636	10/22/2012 11/20/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ARLENE MORALES BURDOCK GROUP	PECAN SHELL FLOUR - RPTS
2012-7637	10/22/2012 11/20/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HENLEY 56354-112, FRANK	ULTRAM (TRAMADOL HCL) - RECS
2012-7638	10/22/2012 12/04/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/ FDA/OMPT/CDRH/OCER/DFOI/	LUKE VELDEERS UNIV OF PENNSYLVANIA/ABRAMSON CANCER CENTER	RESEARCH STUDIES THAT HAVE BEEN GRANTED A WAIVER OF INFORMATION CONSENT THAT ARE IN THE EMERGENCY MEDICAL SETTING PURSUANT TO 21CFR50.24 - TITLE OF STUDY, NAME OF INVESTIGATOR. EMAIL ADDRESS, ETC
2012-7639	10/22/2012 11/20/2012	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	CLAUDIA HORNBACK ROANOKE TRADE SERVICES INC	CHUENEG INC - NOTICES OF FDA REFUSAL ENTRY 53601525388
2012-7640	10/22/2012 11/20/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	SAMUEL F COLIN MD FIRST MANHATTAN CO	LUITPOLD PHARMACEUTICALS INC, SHIRLEY, NY - 483S 1/1/10 TO 10/17/62
2012-7641	10/22/2012	FDA/OMPT/CBER/OCOD/DDOM/		INDIVIDUAL RECS

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	12/06/2012	ALFB/	Doe J	
2012-7642	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jillian Keenan More Magazine	COMPOUNDED PRODUCTS - AERS
2012-7643	10/22/2012 11/20/2012	ORA/ORO/DFI/ ORA/ORO/DFI/	Stephen Watson The Buffalo News	APP PHARMACEUTICALS, GRAND ISLAND, NY - RECORDS RELEASED UNDER FOIA 10/19/02-10/19/12
2012-7644	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	CORIN USA	K904448
2012-7645	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Suzanne O'Shea FAEGRE BAKER DANIELS	NDA 20845 - FORM 3542/3542a FOR PATENT 8,282,966 AND RELATED CORR
2012-7646	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John M. Nardo MD John M. Nardo MD	PROZAC - INITIAL MEDICAL REVIEWS 1987
2012-7647	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OC/OES/ OC/COS/OL/ OC/OCC/ OC/OL/	Tom Burton THE WALL STREET JOURNAL	NECC, FRAMINGHAM, MASS - ALL RECS RE NECC AND MENINGITIS OUTBREAK (10/04/2012 - PRESENT)
2012-7648	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John M. Nardo MD John M. Nardo MD	PAXIL - INITIAL REVIEWS FOR APPROVAL
2012-7649	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth Douville Vertex Pharmaceuticals	MICRO-SPHERE SA - QAP

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Incorporated	
2012-7650	10/22/2012 11/20/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Schnabel FAEGRE BAKER DANIELS	NDA 19430 - FORM 3542/3452A FOR PATENT 7449012, 7794432, 8048035
2012-7651	10/22/2012 11/20/2012	ORA/ ORA/	Christopher Weaver THE WALL STREET JOURNAL	ST JUDE MEDICAL, SYLMAR, CA - 483, EIR, EXHIBITS
2012-7652	10/22/2012 11/20/2012	ORA/ ORA/	RBC CAPITAL MARKETS	ST JUDE MEDICAL, SYLMAR, CA - 483 10/01/2012 - 10/19/2012
2012-7653	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Christopher Wilson NovioSense BV	MEDTRONIC CONTINUOUS GLUCOST MONITORING SYSTEMS RE PARADIGN REAL-TIME SYSTEM AND GUARDIAN REAL-TIME SYSTEM (P980022 S001 TO S122)
2012-7654	10/22/2012 11/20/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mr. Juha-Pekka Nuutinen Ozics Oy	K0909435
2012-7655	10/22/2012 11/20/2012	FDA/OF/CFSAN/OCD/EOS/	Kevin Goldberg Goldberg, Kevin I	MONSTER ENERGY DRINKS - AERS 01/01/2004 - 10/20/2012
2012-7656	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	DIET PEPSI - CAERS 2004 TO PRESENT
2012-7657	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Clarice Arruda Procedure Products Inc.	K884885
2012-7658	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Brian Hartman ABC NEWS	MONSTER ENERGY DRINK - AERS 01/01/2009 - 10/22/2012
2012-7659	10/23/2012 11/21/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Tommy Bottoms LifePoint, INC.	LIFEPOINT, INC. WEST COLUMBIA, SC - EIR
2012-7660	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121598
2012-7661	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	RED BULL - CAERS 2004 TO PRESENT
2012-7662	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	ROCKSTAR ENERGY - CAERS 2004 TO PRESENT
2012-7663	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	GOLDMAN SACHS	ENERGY DRINKS - FIVE HEALTH CASES REFERENCED BY NEW YORK TIMES
2012-7664	10/23/2012	FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson	BLA 103949 S5153

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	11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	
2012-7665	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	COCA COLA, COKE, DIET COKE, ETC - CAERS 2004 TO PRESENT
2012-7666	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	MOUNTAIN DEW - CAERS 2004 TO PRESENT
2012-7667	10/23/2012 11/21/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	GENZYME, FRAMINGHAM, MA - 483, EIR, CORR 2005; GENZYME, ALLSON LANDING, MA - 483, EIR, CORR 2005
2012-7668	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	DR PEPPER - CAERS 2004 TO PRESENT
2012-7669	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Edward McPike	MONSTER ENERGY DRINKS - AERS
2012-7670	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	STARBUCKS - CAERS 2004 TO PRESENT
2012-7671	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	FORBES MAGAZINE	MONSTER ENERGY DRINKS - DEATH REPORTS
2012-7672	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	5 HOUR ENERGY PRODUCTS - CAERS 2004 TO PRESENT
2012-7673	10/23/2012 11/21/2012	FDA/OGROP/ORA/ORO/DIOP/	Frank Bednarz GOODWIN PROCTER LLP	IMPORTATION OF DESMOPRESSIN DRUG PRODUCTS SENT BY FERRING
2012-7674	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	EMILY MADOFF WOLF POPPER ROSS WOLF & JONES, L.L.P.	CORR RE WARNING LTR 9/7/12 TO LANCOME USA
2012-7675	10/23/2012 11/21/2012	CVM/OCD/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	PATRON FARMS LLC, CANFIELD, OH - NON COMPLIANCE RECS, INVESTIGATIONS, WARNING LTRS SINCE 1/09 TO PRESENT
2012-7676	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUSTIN LOVELACE TELEFLEX MEDICAL	PARKER MEDICAL INC - FLEX TIP TRACHEAL TUBE K984528; K100546
2012-7677	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Synergy Pharmaceuticals, nc.	FDA SMG 4850.7
2012-7678	10/23/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger	MONSTER ENERGY - COMPLAINTS OF INJURY/DEATH

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	11/21/2012		Kristy A. Schlesinger	
2012-7679	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	STARBUCKS CAFFEINATED BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7680	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	RED BULL ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7681	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	ROCKSTAR ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7682	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	FULL THROTTLE ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7683	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	AMP ENERGY BEVERAGE - COMPLAINTS OF INJURY/DEATH
2012-7684	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kristy A. Schlesinger Kristy A. Schlesinger	5 HOUR ENERGY - COMPLAINTS OF INJURY/DEATH
2012-7685	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ana Mlinar MESI, d.o.o.	K103693
2012-7686	10/23/2012 11/21/2012	FDA/OF/CFSAN/OCD/EOS/	Lara Yunaska INSIDE EDITION	MONSTER ENERGY DRINKS - AERS 2007 TO PRESENT
2012-7687	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	Jonathan Rockoff THE WALL STREET JOURNAL	NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE, ALAUNUS, ETC - WARNING LETTERS, 483, ETC (01/01/1980 - 10/22/2012)
2012-7688	10/23/2012 11/21/2012	FDA/OC/OES/ OC/COS/OL/ OC/OCC/ FDA/OC/OES/DFOI/ ORA/ ORA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Todd Wallack BOSTON GLOBE	NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE, ALAUNUS PHARMACEUTICAL -- COMPLAINTS, INSPECTION RECS, CORR, ETC (01/01/2002 - 10/22/2012)

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		OC/OL/		
2012-7689	10/23/2012 11/21/2012	FDA/OC/OES/DFOI/	NICHOLS, JARROD	INDIVIDUAL RECS
2012-7690	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ OC/OCC/ ORA/ ORA/ OC/OL/	JUSTIN A. BROWNE, Esq. JANET, JENNER & SUGGS, LLC	NEW ENGLAND COMPOUNDING CTR - NVESTIGATION, WARNING LTR CORR, FUNGAL MENINGITIS OUTBREAK OF 2012 RECS, TEST RESULTS
2012-7691	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ OC/OCC/ ORA/ ORA/ OC/OL/	SEAN HIGGINS, Esq. ANDREWS & THORNTON	NEW ENGLAND COMPOUNDING CTR - MENINGITIS OUTBREAK RECS, MENINGITIS OUTBREAK FROM METHYLPREDNISOLONE, STERIOD INJ AERS, ETC
2012-7692	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CORRENS, DOERTE	ISRS 2000 TO PRESENT - RPT TYPE, GENDER, MFR, ETC
2012-7693	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHIPMAN,, KIM	ISR 39770970001
2012-7694	10/23/2012 11/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	CMPLNT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-7695	10/23/2012 11/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHN D. BRANSON PARKER POE ET AL LLP	MP70 INTELLIVUE - MDRS
2012-7696	10/23/2012 11/21/2012	OM/OMP/DODM/	ANGEL N. MOORE HENRY SPIEGEL MILLING LLP	DOC 44, 77N-0094
2012-7697	10/24/2012 11/22/2012	FDA/OF/CFSAN/OCD/EOS/	BILL KIRK Bill Kirk c/o UBS	MONSTER BEVERAGE CORP - AERS
2012-7698	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21660 S 31
2012-7699	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ OC/OCC/ ORA/ ORA/ OC/OL/	Tom Burton THE WALL STREET JOURNAL	NEW ENGLAND COMPOUNDING CENTER - CORR, MEMOS, INSPECTIONS, ETC (12/05/2006 - 10/03/2012)
2012-7700	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Xuan Liang Devon Medical Products	P910066
2012-7701	10/24/2012 12/21/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Fabian Zaccardo PROFESSIONAL COMPOUNDING CENTERS OF AMERICA (PCAA)	PROFESSIONAL COMPOUNDING CENTER OF AMERICA, HOUSTON, TX - 483, EIR, WARNING LETTERS, ETC (01/01/1990 - 10/01/2012)

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2012-7702	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Xuan Liang Devon Medical Products	P850007, S14, S16, S17
2012-7703	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Parker Theuninck Meagher & Geer, P.L.L.P.	ALAVEN PHARMACEUTICALS, LCC - CORR RE REGLAN INVESTIGATION, BOXED WARNING
2012-7704	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	Kathleen McNerney WBUR	NEW ENGLAND COMPOUNDING CENTER - CORR WITH FDA 01/01/1999 - 10/23/2012
2012-7705	10/24/2012 11/22/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Frank Truslow INDIVIDUAL	ENDO HEALTH SOLUTIONS HUNTSVILLE, AL - INSPECTION RECS 09/01/2010 - 12/31/2012
2012-7706	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	marjo gazak ELI LILLY AND COMPANY - PHARMACEUTICAL DIVISION	NDA 020599; PERIPHERAL AND CNS DRUGS ADVISORY COMMITTEE BRIEFING MATERIALS, MINUTES 09/18/95
2012-7707	10/24/2012 11/22/2012	FDA/OF/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	PEPSI CO - CAERS (01/01/2004 - 10/23/2012)
2012-7708	10/24/2012 11/22/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Frank Truslow INDIVIDUAL	QUALITEST, HUNTSVILLE, AL; QUALITEST, CHARLOTTE, NC - WARNING LETTER, 483, ETC (01/01/2009 - 12/31/2012)
2012-7709	10/24/2012 11/22/2012	FDA/OF/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	COCA COLA - CAERS (01/01/2004 - 10/23/2012)
2012-7710	10/24/2012 11/22/2012	FDA/OF/CFSAN/OCD/EOS/	Sharon Riley CONSUMER REPORTS ON HEALTH	NAIL POLISH, NAIL POLISH REMOVER, ARTIFICIAL NAILS, ETC - CAERS (01/01/2011 - 10/22/2012)
2012-7711	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	Susan Anthoney AEGIS REGULATORY INC	K120775
2012-7712	10/24/2012 11/22/2012	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	Tim McGlinn U. S. Steel & Carnegie Pension	2012-6462

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			Fund	
2012-7713	10/24/2012 11/22/2012	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	PHILIP MORRIS INTERNATIONAL - MODIFIED RISK TOBACCO PRODS RECS
2012-7714	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NORBERT GOTTESMAN AVET CAPITAL MANAGEMENT LLC	AZACITIDINE - DISSOLUTION TEST METHOD RECS; DECITABINE INJ - BIOEQV REQUIREMENTS
2012-7715	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCALES, DESSIE R	AMLODIPINE BESYLATE, ASPIRIN, JANUVIA, ETC - AERS
2012-7716	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTODOULOPOULOS VASSILIOS SANDOZ CANADA INC.	NDA 22-434/S012 - RECS
2012-7717	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUN LIMLENGCO MCGUFF PHARMACEUTICALS INC	MYLAN INSTITUTIONAL LLC, CO GALWAY, IRELAND, KILROE EAST, INVERIN, ETC - EIR, SUMMARY RPT 3/12
2012-7718	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUN LIMLENGCO MCGUFF PHARMACEUTICALS INC	BIONICHE PHARMA, KILROE EAST, INVERIN, CO GALWAY, IRELAND - SUMMARY RPT, EIR 10/09
2012-7719	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHERYL A FISHER TIANO O'DELL	HYCODAN - AERS, MEDICATION ERROR RPTS
2012-7720	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHERYL A FISHER TIANO O'DELL	TUSSINEX (TUSSIONEX) - AERS, MEDICATION ERROR RPTS
2012-7721	10/24/2012	FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE	PHILIP GOLD, SWEDISH CANCER INSTITUTE, SEATTLE, WA - EIRS, 483, CORR 10/10 TO PRESENT

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	11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Celgene Corporation	
2012-7722	10/24/2012 11/22/2012	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	STEPHEN HANAUER, UNIV CHICAGO HOSPITAL MED CTR, CHICAGO, IL - 483 8/05 TO PRESENT
2012-7723	10/24/2012 11/22/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	PATRICIA L REGENYE Celgene Corporation	OLIVIER RIXE, UNIV OF CINCINNATI CANCER INSTITUTE, CINCINNATI, OH - 483S 1/03 TO PRESENT
2012-7724	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	ALESSANDRO TESTORI, ISTITUTO EUROPEO DI 1440, MILANO, ITALY - EIRS, 483S, CORR7/11 TO PRESENT
2012-7725	10/24/2012 11/22/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	MARK KIRSCHBAUM, CITY OF HOPE NATIONAL CANCER CENTER, DUARTE, CA - 483S 4/09 TO PRESENT
2012-7726	10/24/2012 11/22/2012	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	SMITH & NEPHEW - BHR BIRMINGHAM HIP RESURFACING SYS PO40033 MEMOS ETC
2012-7727	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	PROMETHAZINE - MEDWATCH FORM 3500
2012-7728	10/24/2012 11/22/2012	FDA/OF/CFSAN/OCDE/EOS/	MARK PIFKO BARON & BUDD PC	AVON PRODUCTS INC - ANEW REVERSALIST NIGHT RENEWAL CREAM, ANEW ULTIMATE 7S NIGHT CREAM, SOLUTIONS LIQUID BRA TONING GEL, ETC RECS
2012-7729	10/24/2012 11/22/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEPHEN D MUMFORD DRPH INTERNATIONAL SERVICES ASSISTANCE FUND	QUINACRINE HCL, IND 74,802 - EPIDEMIOLOGY RVW RECS
2012-7730	10/24/2012 11/22/2012	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	GERALD J OREHOSTKY ANTARES PHARMA INC	PHARMACEUTICS INTERNATIONAL INC - EIRS, 483S 1/06 TO PRESENT
2012-7731	10/24/2012 11/22/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT P CHARROW GREENBERG TRAURIG LLP	W L GORE & ASSOCIATES INC - GORE-TEX TISSUE REINFORCEMENT PATCH K820193, GORE-TEX SOFT TISSUE PATCH K914449, K930822, ETC
2012-7732	10/25/2012 11/23/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Andrew T. Ryan Ryan Law, APLC	BOSTON SCIENTIFIC/GUIDANT - PACEMAKER INSPECTIONS; GUIDANT VITALITY 2 DR ICD IMPLANT MODEL T165; COMMUNICATIONS RE RECALL ETC

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		FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORAP/SE-FO/SJN-DO/SJN-CB/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-7733	10/25/2012 11/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Wendy Tian LUNDBECK INC	NDA 20593 - SBA
2012-7734	10/25/2012 11/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Diana Rogers Diana Rogers	ELECON CREAM NDA REVIEWS
2012-7735	10/25/2012 11/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Barbara Swift UNIVERSITY OF FLORIDA	TERIFLUNOMIDE - SBA
2012-7736	10/25/2012 11/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Diana Rogers Diana Rogers	ELOCON OINTMENT NDA REVIEWS
2012-7737	10/25/2012 11/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Diana Rogers Diana Rogers	ELECON LOTION NDA REVIEWS
2012-7738	10/25/2012 11/23/2012	FDA/OF/CFSAN/OCDE/EOS/	Chris Lahiff McDermott Will & Emery LLP	MONSTER BEVERAGES - AERS (01/01/2004 - 10/24/2012)
2012-7739	10/25/2012 11/23/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OC/OCC/	Tom Burton THE WALL STREET JOURNAL	COMPOUNDING PHARMACIES - EMAILS, MEMORANDA, LEGAL ANALYSES, ETC BETWEEN OCC AND CDER COMPLIANCE

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2012-7740	10/25/2012 11/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kurt Greve Kurt W. Greve	NDA 21817 S 12
2012-7741	10/25/2012 11/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert DeGaetano Robert DeGaetano	METFORMIN - CLINICAL STUDIES RE B12 DEFICIENCY
2012-7742	10/25/2012 11/23/2012	FDA/OC/OES/DFOI/	Daniel Balaban Daniel Balaban	MCNEIL, JOHNSON & JOHNSON - TYLENOL INSPECTIONS, RECALL OF 2010, RESPONSE TO INVESTIGATION, ETC
2012-7743	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	Keith Leland Preceptis Medical, Inc.	K103595
2012-7744	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	QIAGEN SCIENCES	GREINER BIO-ONE GMBH - EIR (1/27/2003 - 01/30/2003)
2012-7745	10/25/2012 11/23/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Susan Dianne Luce Luce, Susan D	PRIDE OF AMERICA CRUISE SHIP HAWAIIAN ISLANDS - MOST RECENT INSPECTION REPORT
2012-7746	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William A. Scofield, Jr. Lathrop & Gage LLP	K021736
2012-7747	10/25/2012 11/23/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	QIAGEN SCIENCES	SCANTIBODIES, SANTEE, CA - EIR 2011
2012-7748	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	William A. Scofield, Jr. Lathrop & Gage LLP	K003323
2012-7749	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	John DeLucia ICAD INC	P100005/S001
2012-7750	10/25/2012 11/23/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125276 S49
2012-7751	10/25/2012 11/23/2012	ORA/ ORA/	JULIA KUFMAN RBC CAPITAL MARKETS	ST JUDE MEDICAL, ARECIBO, PR - 483 (10/02/2012 - 10/02/2012)
2012-7752	10/25/2012 11/23/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL ASSOC INC, GREENVILLE, SC - 483 9/12
2012-7753	10/25/2012	FDA/OGROP/ORA/CE-FO/BLT-	JOHNATHAN RICKMAN	CB FLEET CO INC, LYNCHBURG, VA; PHIPPS & BIRD INC,

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	11/23/2012	DO/BLT-CB/	FDANEWS	RICHMOND, VA; INVITROCARE INC, FREDERICK, MD - 483 9/12
2012-7754	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BLUE ISLAND PHENOL LLC, BLUE ISLAND, IL; MEDGYN PRODUCTS INC, ADDISON, IL; RICHARD WOLF MEDICAL INSTRUMENTS CORP, VERNON HILLS, IL - 483 9/12
2012-7755	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH 414 LLC, WEST CHESTER, OH; KUTOL PRODUCTS CO, SHARONVILLE, OH; MEAS US LLC, DAYTON, OH - 483 9/12
2012-7756	10/25/2012 11/23/2012	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	ISO TEC DIAGNOSTICS INC, FRIENDSWOOD, TX; ST JUDE MEDICAL, PLANO, TX - 483 9/12
2012-7757	10/25/2012 11/23/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	AMERICAN SLEEP ASSOC LLC, CEDAR CITY, UT; LED TECHNOLOGIES LLC, ELIZABETH, CO - 483 9/12
2012-7758	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	ELBA INC, TROY, MI; BAXTER PHARMACEUTICALS SOLUTIONS LLC, BLOOMINGTON, IN; AIRGAS GREAT LAKES LLC, LANSING, MI - 483 9/12
2012-7759	10/25/2012 11/23/2012	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	VITAL PHARMACEUTICALS INC, WESTON, FL; AMERICAN NATURAL PRODUCTS INC, MIAMI, FL; INVIVO CORP, ORLANDO, FL - 483 9/12
2012-7760	10/25/2012 11/23/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	PFIZER HEALTH AB, STRANGNAS, SWEDEN; KANEBO COSMETICS INC, ODAWARA SHI KANAGAWA, JAPAN; AJANTA PHARMA LTD, AURANGABAD, INDIA - 483 9/12
2012-7761	10/25/2012 11/23/2012	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	SEIKAGAKU CORP, IBARAKI, JAPAN; BPTRU MEDICAL DEVICES, COQUITAM, CANADA; SIGVARIS DO BRASIL, JUNDIAI, BRAZIL - 483 9/12
2012-7762	10/25/2012 11/23/2012	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARE TECH LABS INC, ST LOUIS, MO; MGP INGREDIENTS INC, ATCHISON, KS; GLOBAL MEDICAL HOLDINGS LLC, ADEL, IA - 483 9/12
2012-7763	10/25/2012 11/23/2012	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	BAXTER HEALTHCARE CORP, LOS ANGELES, CA; TITAN MEDICAL ENTERPRISES INC, SANTA FE SPRINGS, CA; IRENDIA CORP, LOS ANGELES, CA - 483 9/12
2012-7764	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	STEUART LABS, MABEL, MN; PETNET SOLUTIONS INC, MINNEAPOLIS, MN; HYDRITE CHEMICAL CO, MILWAUKEE, WI - 483 9/12
2012-7765	10/25/2012 11/23/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH 414 LLC, WOBURN, MA; APLICATE INC, MERIDEN, CT; DAVOL INC, WARWICK, RI - 483 9/12
2012-7766	10/25/2012 11/23/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	JAMES ALEXANDER CORP, BLAIRSTOWN, NJ; LTS LOHMAN THERAPY SYS CORP, WEST CALDWELL, NJ; WATER JEL TECHNOLOGIES LLC, CARLSTADT, NJ - 483 9/12

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2012-7767	10/25/2012 11/23/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	DR REDDYS LABORATORIES LLC, SHREVEPORT, LA; ORAL DNA LABS INC, BRENTWOOD, TN - 483 9/12
2012-7768	10/25/2012 11/23/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH 414 LLC, ROCHESTER, NY; CHARTWELL PHARMS, CONGERS, NY; STERI PHARMA LLC, SYRACUSE, NY - 483 9/12
2012-7769	10/25/2012 11/23/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	HIGH CHEMICAL CO, LEVITTOWN, PA; MERCK SHARPE & DOHME CORP, WEST POINT, PA; GLYCADIA INC, PHILADELPHIA, PA - 483 9/12
2012-7770	10/25/2012 11/23/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARDINAL HEALTH LLC, LAS VEGAS, NV; MIZUHO OSI, UNION CITY, CA; OPTOVUE INC, FREMONT, CA - 483 9/12
2012-7771	10/25/2012 11/23/2012	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	TAPI PUERTO RICO INC, GUAYAMA, PR - 483 9/12
2012-7772	10/25/2012 11/23/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	WELCH ALLYN PROTOCOL INC, BEAVERTON, OR - 483 9/12
2012-7773	10/25/2012 11/23/2012	ORA/ ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	KASIOS BONE SUBSTITUTES, LAUNAGUET, FRANCE; AUS SYSTEMS PTY LTD; ALLENBY GARDENS, AUSTRALIA; STEELCO SPA, RIESE PIO X, ITALY - 483 9/12
2012-7774	10/26/2012 11/26/2012	ORA/ ORA/	Amy Birnbaum CBS NEWS	NEW ENGLAND COMPOUNDING CENTER - 483, EIR, MEDWATCH REPORTS, ETC
2012-7775	10/26/2012 11/26/2012	ORA/ ORA/	LAZARD CAPITAL MARKETS	ST JUDE MEDICAL, SYLMAR, CA - 483, CORR (09/01/2012 - 10/25/2012)
2012-7776	10/26/2012 11/26/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Boehringer Ingelheim	GARY SCHILLER, UCLA MEDICAL CENTER - 483 2001, 2011
2012-7777	10/26/2012 11/26/2012	FDA/OF/CFSAN/OCD/EOS/	Ricky Campbell Register Citizen	ENERGY DRINKS, K2 - AERS IN CONNECTICUT
2012-7778	10/26/2012 11/26/2012	OM/OMP/DODM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2011-P-0573 - COMMENTS TO DOCKET
2012-7779	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anna Edney BLOOMBERG NEWS	NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA - AERS, WARNING LETTERS, INSPECTION REC

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		FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/		
2012-7780	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071343
2012-7781	10/26/2012 11/26/2012	FDA/OO/OFBA/OAGS/	Ryan Fothergill Primus Labs	FDA AGREEMENTS WITH IEH INTERNATIONAL (05/01/2009 - 10/25/2012)
2012-7782	10/26/2012 11/26/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NATHANIEL ENOS CONWAY HOMER & CHIN- CAPLAN PC	VAERS - INDIVIDUAL RECS
2012-7783	10/26/2012 11/26/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	MONSTER ENERGY PRODS - CAERS
2012-7784	10/26/2012 11/26/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	VAERS - INDIVIDUAL RECS
2012-7785	10/26/2012 11/26/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 157049
2012-7786	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	VINEET SARIN PHD KINAMED INC	K954219, K954213, K922247, ETC
2012-7787	10/26/2012 11/26/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	WILLIAM S JOHNSON RN FLORIDA MEDICAL CLINIC	FLORIDA MEDICAL CLINIC, ZEPHYRHILLS, FL - AUDIT 8/6/12
2012-7788	10/26/2012 11/26/2012	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/	DONALD E SEGAL ESQ ALSTON & BIRD LLP	USE OF LASER-ETCHING TECHNOLOGY ON EGGS AND A WALMART PILOT PROGRAM PERMITTING THE REPACKING OF EGGS AT THE RETAIL LEVEL - RECS, CORR
2012-7789	10/26/2012 11/26/2012	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	LEIF LARSEN CBC MANITOBA	FRESH HEMP FOODS LTD - HEMP BLISS (NON DAIRY HEMP BEVERAGE) IMPORT REFUSAL RECS
2012-7790	10/26/2012 11/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUSTIN D RIEGER ROBBINS UMEDA LLP	POLYMEDIX INC - PMX-60056 CLNCL TRIAL APRVL RECS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-7791	10/26/2012 11/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ OC/OCC/ ORA/ ORA/ OC/OL/	SEAN HIGGINS ESQ ANDREWS & THORNTON	ALANIS PHARM - METHYLPREDNISOLONE ACETATE MEMINGITIS OUTBREAK RECS 2012; AMERIDOSE LLC - STEROID INJ AERS 1/12 TO PRESENT, ETC
2012-7792	10/26/2012 11/26/2012	ORA/ ORA/ OC/OER/OPA/	M MELISSA BALTZ BUTLER SNOW ET AL	J&J MARKETED VAGINAL MESH IMPLANT WITHOUT US APPROVAL - CORR (CERTIFIED)
2012-7793	10/26/2012 11/26/2012	ORA/ ORA/ OC/OER/OPA/	M MELISSA BALTZ BUTLER SNOW ET AL	J&J SOLD VAGINAL MESH IMPLANT AFTER SALES HALT ORDERED - CORR (CERTIFIED)
2012-7794	10/26/2012 11/26/2012	ORA/ ORA/	KEVIN STRANGE WELLS FARGO SECURITIES	ST JUDE MEDICAL, SYLMAR, CA - 483 9/25/12-10/17/12
2012-7795	10/26/2012 11/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	NAPRELAN (NAPROXEN SODIUM) NDA 20-353 - SBA
2012-7796	10/26/2012 11/26/2012	ORA/ORM/ ORA/ORM/	DAVID MANGIONE FDAZILLA	483S 8/23/12-10/24/12
2012-7797	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/ ORA/ ORA/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ST JUDE MEDICAL, SYLMAR, CA - EIRS, 483S, WARNING LTRS, ETC 1/12 TO PRESENT
2012-7798	10/26/2012 11/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUN LIMLENGCO MCGUFF PHARMACEUTICALS INC	BIONICHE PHARMA, KILROE EAST, INVERIN, CO GALWAY, IRELAND - EIR 10/09; MYLAND INSTITUTIONAL LLC, KILROE EAST, INVERIN, CO GALWY, IRELAND - EIR 3/12
2012-7799	10/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN	JENERIC/PENTRON INC - QUELL DESENSITIZER RECS

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	11/26/2012	FDA/OC/OES/DFOI/	HARVEST CONSULTING CORP	
2012-7800	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HERAEUS KULZER LLC - GLUMA DESENSITIZER POWER GEL RECS
2012-7801	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	COLGATE-PALMOLIVE CO - COLGATE DESENSITIZING DENTAL CREAM RECS
2012-7802	10/26/2012 11/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALLISON CHEN HARVEST CONSULTING CORP	HOENIX DENTAL INC - SUPER SEAL TOOTH DESENSITIZER RECS
2012-7803	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	AMAG PHARMACEUTICALS INC - FERAHEME (FERUMOXTOXOL INJ) NDA 22-180 AERS 10/09 TO PRESETN
2012-7804	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	WATSON PHARMS - NULECIT (IRON GLUCONATE & FERRIC GLUCONATE) ANDA 78-215 SBA 10/09 TO PRESENT
2012-7805	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	SANOFI-AVENTIS - FERRLECIT (IRON GLUCONATE & FERRIC GLUCONATE) NDA 17-44 SBA 10/09 TO PRESENT
2012-7806	10/26/2012 11/26/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	LUITPOLD PHARMACEUTICALS INC - VENOFER (IRON SUCROSE INJ) NDA 21-135 SBA 10/09 TO PRESENT
2012-7807	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/1-5/12
2012-7808	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 9/24-28/12
2012-7809	10/26/2012 11/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/8-12/12
2012-7810	10/29/2012 11/27/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ram Mohan Kathuroju INVAGEN PHARMACEUTICALS INC	ANDA 075753 - SBA

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2012-7811	10/29/2012 11/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACOB JACOBSEN DUKE UNIVERSITY	5-HTP - AERS
2012-7812	10/29/2012 11/27/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Ricky Campbell Journal Register Co.	NATUREMOST OF NEW ENGLAND, MIDDLETOWN, CT - CORR RE WARNING LETTER (05/24/2012 - 10/25/2012)
2012-7813	10/29/2012 11/27/2012	FDA/OF/CFSAN/OCD/EOS/	Barry Meier New York Times --Barry Meier	DIETARY SUPPLEMENTS - AERS (12/01/2008 - 10/01/2012); FDA NOTIFICATION OF AFFECTED COMPANIES OF RECEIPT OF FATALITY
2012-7814	10/29/2012 11/27/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATIONS - CORR, DOCUMENTATION, SUMMARIES (08/01/12 TO 10/29/12)
2012-7815	10/29/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Essex Industries, Inc.	K833994
2012-7816	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6222
2012-7817	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6055
2012-7818	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5914
2012-7819	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5887
2012-7820	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5683
2012-7821	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6309
2012-7822	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6250
2012-7823	10/30/2012 11/28/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6225
2012-7824	10/31/2012 11/29/2012	FDA/OF/CFSAN/OCD/EOS/	JEFFREY BARRACK Jeffrey Barrack	MONSTER ENERGY DRINKS - AERS; DEATH REPORTS (11/07 TO PRESENT)
2012-7825	10/31/2012 11/29/2012	ORA/ ORA/	Triunfo-Mex, Inc.	M42-3142497-7 - TEST RESULTS

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2012-7826	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	Doe J	SMITH AND NEPHEW - CORR WITH FDA RE BIRMINGHAM HIP RESURFACING DEVICE
2012-7827	10/31/2012 11/29/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Law Offices of Ronald A. Marron	HYLAND'S INC, STANDARD HOMEOPHATHIC CO - CORR WITH FDA RE CALMS FORTE, TEETHING TABLETS, MIGRAINE HEADACHE RELIEF, ETC
2012-7828	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sheffield, Deborah	K965001
2012-7829	10/31/2012 11/29/2012	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (09/27/2012 - 10/26/2012)
2012-7830	10/31/2012 11/29/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ ORA/ORM/ ORA/ORM/ ORA/ ORA/	GMP Training Materials	FDA INVESTIGATOR TRAINING COURSE MATERIAL; DRUG GMP TRAINING COURSE MATERIAL (01/01/2011 - 10/26/2012)
2012-7831	10/31/2012 11/29/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	IPD ANALYTICS LLC	ANDA 091347 - EFFECTIVE APPROVAL LTR
2012-7832	10/31/2012 03/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Kelly Cycon Zeptometrix (Formerly Cellular Products)	CELLULAR PRODUCTS HIV AND HTLV DIAGNOSTIC KITS - APPROVAL RECORDS (01/01/1985 - 12/31/1989)
2012-7833	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Seawon Meditech Co., Ltd.	K111593
2012-7834	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring Quality & Regulatory Associates,	K082474

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2012-7835	10/31/2012 11/29/2012	FDA/OF/CFSAN/OCD/EOS/	Robert MacArthur Alternative Research Services, Inc.	MONSTER BEVERAGE CORP - REPORTS, INVESTIGATIONS, CORR
2012-7836	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lia Obata Dowd Dowd & Dowd, PC	BOEHRINGER INGELHEIM PHARM, INC; BOEHRINGER INGELHEIM CORP; BOEHRINGER INGELHEIM USA, ETC - PRADAXA RECS, APPLICATIONS, AERS, ETC
2012-7837	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 201803
2012-7838	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS -ISR 8404106-1
2012-7839	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR NUMBERS 6673059-9, 6691992-9, 6709086-2 ETC
2012-7840	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7267891-0, 8058598-0, 8099049-X ETC
2012-7841	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HARPER #34654, JOHNATHAN SETH	PCP - AERS
2012-7842	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALAIN NIGON ALN IMPLANTS CHIRURGICAUX	WILLIAM COOK EUROPE APS - COOK CELECT VENA CAVA FILTER AND GUNTHER TULIP VENA CAVA FILTER RETRIEVAL SET K073374
2012-7843	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CAROL DRURY ENDOMETRIOSIS ASSOCIATION	NUMBER OF THERAPIES APPROVED BY THE FDA FOR THE TREATMENT OF ENDOMETRIOSIS

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2012-7844	10/31/2012 11/29/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/COS/OES/ OC/COS/OES/ OM/OMP/DODM/	LEIGH A SANDERS CENTER FOR RESPONSIBLE SCIENCE	DKTS 2007P-0109, 2007P-0457; DRAFT GUIDANCE TO INDUSTRY REGARDING NON-ANIMAL TESTS FOR DRUG DEVELOPMENT PROGRAMS, ETC
2012-7845	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTERPRO LITE, INTEXEN LP K082730 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 11/26/08 (CERTIFIED)
2012-7846	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - AMS ELEVATE WITH INTEPRO LITE PROLAPSE REPAIR SYS, AMS ELEVATE WITH INTEXEN LP PROLAPSE REPAIR SYS K080185 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 4/10/08 (CERTIFIED)
2012-7847	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMEICAN MEDICAL SYSTEMS - AMS APOGEE VAULT SUSPENSION SYS K040537 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 4/.22/04 (CERTIFIED)
2012-7848	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - APOGEE AND PERIGEE SYSTEMS WITH INTEPRO LITE AND INTEXEN LP PELVIC FLOOR REPAIR SYS K082387 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 12/4/08 (CERTIFIED)
2012-7849	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BARD UROLOGICAL DIVISION - AVAULTA SOLO SUPPORT SYS, AVAULTA PLUE BIOSYNTHETIC SUPPORT SYS K063712 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 3/27/07 (CERTIFIED)
2012-7850	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BOSTON SCIENTIFIC CORP - PINNACLE PELVIC FLOOR REPAIR KIT K071957 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 1/13/09 (CERTIFIED)
2012-7851	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BARD UROLOGICAL DIVISION - AVAULTA SOLO SUPPORT SYS, AVAULTA PLUS BIOSYNTHETIC SUPPORT SYS K082571 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 9/30/08 (CERTIFIED)
2012-7852	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	BOSTON SCIENTIFIC CORP - TBD SURGICAL MESH DVC K081048 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 8/22/08 (CERTIFIED)
2012-7853	10/31/2012 11/29/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS - APOGEE AND PERIGEE SYTEMS WITH PC COATED INTEPRO LITE K081710 (CERTIFIED); SUBSTANTIAL EQUIVALENCE LTR 10/15/08 (CERTIFIED)

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2012-7854	10/31/2012 11/29/2012	OC/OM/OMP/DDM/	THOMAS D. FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT FDA-2012-P-0632, FDA-2012-P-1018
2012-7855	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sevrina Ciucci Sevrina Ciucci	K061268
2012-7856	11/01/2012 11/30/2012	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Doe J	CONSUMER COMPLAINT RECS
2012-7857	11/01/2012 11/30/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ CVM/OCD/	Shane Baker Joint Investments LLC	MASCOMA CORP - RECOMBINANT YEAST PRODUCTS
2012-7858	11/01/2012 11/30/2012	FDA/OC/OES/DFOI/	Todd Wallack BOSTON GLOBE	NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE - FOIA REQUESTS, RESPONSES (01/01/2004 - 10/30/2012)
2012-7859	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Michael P. Krensavage Krensavage Asset Management	RTI BIOLOGICS, ALACHUA, FL - WARNING LETTER RECS
2012-7860	11/01/2012 11/30/2012	FDA/OC/OES/DFOI/	Jared MacCleary CROWELL & MORING	FOIA LOGS FOR CVM (04/01/2012 - 10/31/2012)
2012-7861	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Jose H. Lebron, Stat Rx QA Manager Stat Rx	STAT RX - 484, 483, EIR (01/01/2006 - 12/31/2011)
2012-7862	11/01/2012 11/30/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	LEERINK SWANN LLC	AUTOGENOMICS, VISTA, CA - EIR (09/01/2009 - 09/22/2009)
2012-7863	11/01/2012 11/30/2012	ORA/ ORA/	Andrew Kahn UNITE HERE	ST JUDE MEDICAL, SYLMAR, CA - 483 (09/01/2012 - 10/30/2012)
2012-7864	11/01/2012 11/30/2012	CVM/OCD/	Rob Varese SHOTWELL & CARR, INC.	TYPE B AND TYPE C MEDICATED FEEDS - MICROBIOLOGICAL ASSAY METHOD
2012-7865	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISA BALTZ BUTLER SNOW ET AL	C R BARD INC, COVINGTON, GA - AVAULTA SOLO SUPPORT SYS & AVAULTA PLUS BIOSYNTHETIC SUPPORT SYS K083839 (CERTIFIED)
2012-7866	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEM, MINNETONKA, MN - AMS ELEVATE PC ANTERIOR & APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE K111118 (CERTIFIED)
2012-7867	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	CALDERA MEDICAL INC, AGOURA HILLS, CA - ASCEND BLUE MESH AC & PC K101462 (CERTIFIED)
2012-7868	11/01/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ	COLOPLAST A/S, HUMLEBAEK, DENMARK - EXAIR

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	11/30/2012		BUTLER SNOW ET AL	ANTERIOR & PROLAPSE REPAIR SYS K112386 (CERTIFIED)
2012-7869	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN - ELEVATE PC ANTERIOR & APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE & ELEVATE PC APICAL & POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE K112842 (CERTIFIED)
2012-7870	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISA BALTZ BUTLER SNOW ET AL	MPATHY MEDICAL DEVICES LTD, RAYNHAM, MA - RESTORELLE POLYPROPYLENE MESH K092207 (CERTIFIED)
2012-7871	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS, MINNETONKA, MN - ELEVATE ANTERIOR & APICAL PROLAPSE REPAIR SYS WITH INEPRO LITE K082677 (CERTIFIED)
2012-7872	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	CALDERA MEDICAL INC, AGOURA HILLS, CA - ASCEND SURGICAL MESH K083722 (CERTIFIED)
2012-7873	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS, MINNETONKA, MN - ELEVATE PROLAPSE REPAIR SYSTEM WITH PC COATED INTEPRO LITE K090713 (CERTIFIED)
2012-7874	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELLISSA BALTZ BUTLER SNOW ET AL	AMERICAN MEDICAL SYSTEMS INC, MINNETONKA, MN - ELEVATE ANTERIOR & APICAL PROLAPSE REPAIR SYS, APICAL & POSTERIOR PROLAPSE REPAIR SYS, APICAL & POSTERIOR PROLAPSE REPAIR SYS WITH INTExEN K121612 (CERTIFIED)
2012-7875	11/01/2012 11/30/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	COLOPLAST A/S, HUMMLEBAEK, DENMARK - EXAIR ANTERIOR & EXAIR POSTERIOR PROLAPSE REPAIR SYS K083499 (CERTIFIED)
2012-7876	11/01/2012 11/30/2012	FDA/OGROP/ORR/SE-FO/SJN-DO/SJN-CB/	AMY WADE NOVARTIS ANIMAL HEALTH	CARDINAL HEALTH PR 410 INC, HUMACAO, PR - EIR 6/07-16/04
2012-7877	11/01/2012 11/30/2012	FDA/OF/CFSAN/OCD/EOS/	DANIEL R LUCKY LUCKY CONSULTANTS LLC	FCN 1162
2012-7878	11/01/2012 11/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L. ROLLO HUSCH BLACKWELL LLP	SANDOZ - OLMESARTAN MEDOXOMIL NDA 90-237 APRVL LTR 9/16/09
2012-7879	11/01/2012 11/30/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L. ROLLO HUSCH BLACKWELL LLP	MYLAN PHARMS INC - OLMESARTAN MEDOXOMIL APRVL 10/3/08, 5/15/12
2012-7880	11/01/2012	FDA/OF/CFSAN/OCD/EOS/	MADHU SONI	CAFFEINE - CAERS 1/05 TO 3/12

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	11/30/2012		SONI & ASSOCIATES INC	
2012-7881	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	CARSTON C. JOHANNSSEN GOULD LAW OFFICES CHTD LLC	OPTIMAL PAIN CONTROL CREAM - AER SINCE 2010
2012-7882	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	CARSTON C. JOHANNSSEN GOULD LAW OFFICES CHTD LLC	DICLOFENAC - AER SINCE 2009
2012-7883	11/01/2012 11/30/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ ORA/OCI/ ORA/OCI/	CARSTON C. JOHANNSSEN GOULD LAW OFFICES CHTD LLC	FRANKLIN PHARMACY, ALABAMA & SHEFFIELD PHAMRCY & HOMECARE, FRANKLIN COUNTY, ALABAMA CONNECTION WITH DANIEL MITCHELL MD, HAWNEE MISSION MEDICAL CTR FOR PAIN MEDICINE, SHAWNEE MISSION, KS - RECS 2009 TO PRESENT
2012-7884	11/01/2012 11/30/2012	CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	PHYTASE - RVW
2012-7885	11/01/2012 11/30/2012	CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	GENENCOR - RVW
2012-7886	11/01/2012 11/30/2012	FDA/OC/OES/DFOI/	CHASTINE 12B2563, JAMES	FDA ORGANIZATIONAL CHART
2012-7887	11/01/2012 11/30/2012	ORA/ ORA/	KATIE THOMAS NEW YORK TIMES	ST JUDE MEDICAL, SYLMAR, CA - 483 10/17/12
2012-7888	11/01/2012 11/30/2012	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PATTI WALLER MARLER CLARK ATTYS	SALMONELLA ENTERIDITIS OUTBREAK 3/00 TO 4/00
2012-7889	11/01/2012 11/30/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MARSHA JAFARY RECKITT BENCKISER INC	FLURBIPROFEN - AER 1/08 TO 10/20/12
2012-7890	11/01/2012 11/30/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ERP/DIDP/	KRISTEN FASO LAW OFFICES OF DAVID W HOLUB	NEW ENGLAND COMPOUNDING PHARMACY - RECALL; LICENSING MENINGITIS PRODUCING STERIOD MEDICATIONS

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2012-7891	11/01/2012 11/30/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GURAL, MARILYN,	HOSPIRA, GUJARAT, INDIA; DR REDDYS, INDIA; SUN PHARMA, INDIA - 483, WARNING LTRS, EIR 1/07 TO 8/12
2012-7892	11/01/2012 11/30/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	MONSTER ENERGY - CAERS; MONSTER ENERGY PRODS 2004 TO PRESENT
2012-7893	11/01/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OC/OES/DFOI/ ORA/ ORA/ FDA/OC/OES/DFOI/	MEG P. DADAY SEDGWICK LLP	CRONOBACTER SAKAZAKII - INVESTIGATION RECS, TESTING DATA, LAB SHEETS, ETC 1/11 TO PRESENT
2012-7894	11/01/2012 11/30/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-	LEIF LARSEN CBC NEWS	CHAMPION PET FOODS - ACANA GRASSLANDS DOG FOOD; STRAUSS HERBS - VITAMINS, MOISTURIZING HERBAL BODY WASH, HERBAL LOTION, ETC; BUNGE CANADA NIPAWIN - CANOLA MEAL, ETC IMPORT REFUSALS

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		DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/		
2012-7895	11/01/2012 11/30/2012	FDA/OF/CFSAN/OCD/EOS/	SCOTT W. ROONEY NEMES ROONEY ET AL	FIVE HOUR ENERGY - CAERS, INVESTIGATION RECS
2012-7896	11/02/2012 12/03/2012	FDA/OF/CFSAN/OCD/EOS/	CARLA R SCARMAZZI King & Spalding LLP	2012-6462, 2012-6463, 2012-6464, 2012-6465
2012-7897	11/02/2012 12/03/2012	FDA/OF/CFSAN/OCD/EOS/	CRAIG ROUSH ROCKLINE INDUSTRIES	LIST OF ACTIVE COSMETIC ESTABLISHMENTS
2012-7898	11/02/2012 12/03/2012	FDA/OO/OFBA/OAGS/ FDA/OC/OES/DFOI/	JEFF STACHEWICZ FOIA GROUP INC	HHSF223200830014I - CONTRACT, MODIFICATION, AMENDMENTS, ETC
2012-7899	11/02/2012 12/03/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DANIEL MACWILLIAMS WILSON ELSEER MOSKOWITZ EDELMAN & DICKER LLP	FRANCK'S COMPOUNDING PHARMACY, OCALA, FL - BACTERIAL AND/OR MICROORGANISM GROWTH TESTING RECS
2012-7900	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elzie L Burgher Burgher, Elzie L	ORENCIA - AERS
2012-7901	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Adam Sanders Adam Sanders, attorney for Insight Pharm	K941765, K936013, K934830 ETC
2012-7902	11/02/2012 12/03/2012	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/	MARK MCAFEE RAW MILK INSTITUTE.ORG	DR GREGORY MILLER PHD, CALIFORNIA DAIRY RESEARCH FOUNDATION - MILK RELATED RESEARCH ACTIVITIES CORR
2012-7903	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO SCHOOL OF MEDICINE	FINASTERIDE, DUTASTERIDE - AERS
2012-7904	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BRENTUXIMAB - AERS

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2012-7905	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	Cynthia McHale Law Firm of McAfee & Taft	DERMAMEDICS, LLC - INVESTIGATION, INSPECTIONS OF LABELING, ADVERTISING, PRODUCT INFORMATION ETC (01/02/2012 - 11/01/2012)
2012-7906	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lavenia Ford Cardinal Health 200, LLC	K000442
2012-7907	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Kelly Joohnson Fabyanske, Westra, Hart & Thomson, P.A.	HOSPIRA, SAN CRISTOBAL, DOMINICAN REPUBLIC - EIR (6/15/2009 - 12/15/2009)
2012-7908	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	SANOPI PASTEUR - IVERMECTIN (SKLICE) LOTION NDA 202-736 SBA, MOR, LBLG, ETC
2012-7909	11/02/2012 12/14/2012	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OES/ OC/COS/OES/	Jim Gearhart QUORUM REVIEW	WESTERN INSTITUTIONAL REVIEW BOARD - CORR WITH FDA RE NEW REGULATIONS (07/01/1981 - 06/30/1982)
2012-7910	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Paul Lee Johnson & Johnson Medical Products	K090821
2012-7911	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Macquarie	ADVATE - AERS (01/01/2000 - 11/01/2012)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/OCOD/DDOM/ ALFB/		
2012-7912	11/02/2012 12/03/2012	FDA/OMPT/CTP/OD/	Aldridge, Kevin	CONTACT INFORMATION FOR CIGARETTE TUBE MANUFACTURER
2012-7913	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahadev Patel R&D Support Services Inc.	XYLO CHEM INDUSTRIES, NADIAD, INDIA - EIR (07/01/2011 - 07/16/2011)
2012-7914	11/02/2012 12/03/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	Dawn M. Chmielewski Climaco Wilcox Peca Tarantino & Garofoli	MIRENA - AERS, DDMAC CORR, ADVISORY COMMITTEE TRANSCRIPTS, ETC (01/01/2000 - 11/02/2012)
2012-7915	11/02/2012 12/03/2012	FDA/OMPT/CDRH/OCER/DFOI/	Jack Cobourn Jack Cobourn	CLOPIDOGREL OR TICLOPIDINE-ELUDING STENTS USED IN ANGIOPLASTIES - AERS (03/01/2008 - 03/30/2010)
2012-7916	11/02/2012 12/03/2012	OC/OM/OMP/DDM/	JEFF GERTH PROPUBLICA	DKT 1977N-0094L
2012-7917	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDANT LIVING AIDS	TRADE CMPLNT - TRACKING NUMBER CPT1100211 CORR 5/12 TO PRESENT
2012-7918	11/05/2012 12/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	UNREDACTED RPTS OF FAERS (AERS) 1/06 TO PRESENT
2012-7919	11/05/2012 12/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH BARBCHENN PUBLIC CITIZEN	ISR 3157839, 3767780, 3775034, ETC
2012-7920	11/05/2012 12/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAHENDER KORAPATI MEDCORE PHARMA LLC	PFIZER -ANTIVERT (MECLIZINE HCL) ORAL TABS 12.5 MG, 25 MG, 50 MG NDA 10-721 APRVL RECS
2012-7921	11/05/2012	FDA/OGROP/ORA/CE-FO/CHI-	NATHAN A BEAVER	LIFESOUTH COMMUNITY BLOOD CENTERS 9/10/10, 7/24/12;

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	12/04/2012	DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	FOLEY & LARDNER LLP	AURORA AREA BLOOD BANK (HEARTLAND) 1/14/10; HEARTLAND BLOOD CENTERS INC, 11/28/11, ETC - 483'S WARNING LTRS, UNTITLED ENFORCEMENT LTRS, ETC
2012-7922	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	BETHANY WALLS Intertek Chemicals and Pharmaceuticals	PPG INDUSTRIES - CO-POLYMER OF METHACRYLIC ACID, ETHYL ACRYLATE, STYRENE, BUTYL METHACRYLATE & GLYCIDYL METHACRYLATE FCN 1177
2012-7923	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 142534, 144083, 144598, ETC
2012-7924	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	ADAMS, JACKSON	MONSTER ENERGY DRINKS - CAERS
2012-7925	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	PATTY LOVERA Food & Water Watch	AMERICAN DAIRY PRODUCTS INSTITUTE & THE US DAIRY EXPORT COUNCIL - GRASS NOTICE 444 MILK PROTEIN CONCENTRATE & MILK PROTEIN ISOLATE 9/25/12
2012-7926	11/05/2012 12/04/2012	FDA/OO/OFBA/OAGS/	PAYAL TAK TELESIS CORP	CHICKASAW NATION PROFESSIONAL SERVICES INC (SRA INTERNATIONAL INC) - HHSF2232009500261
2012-7927	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	CHRISTY CASPERS COPPERLEAF KITCHEN	COPPERLEAF KITCHEN, ALEXANDRIA, MN - NONPUBLIC RECS NAME OF FIRM, LTR DESTROY ALL HARD COPIES
2012-7928	11/05/2012 12/05/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	NUTRA MANUFACTURING, GREENVILLE SC 3/3-8/11; EVOL NUTRITION, KENNESAW, GA 7/13-29/11; VALENTINE ENTERPRISES INC, LAWRENCEVILLE, GA 10/5-11/11, ETC EIRS, 483S

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		FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OC/OES/DFOI/		
2012-7929	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	LOVATE - HYDROXYCUT, SMARTBURN, RAPIDSLIM & RAPID SLIM, ETC CAERS 8/2/12 TO PRESENT
2012-7930	11/05/2012 12/04/2012	ORA/ ORA/	RICHARD D NEWMAN PHD RND SERVICES LLC	AMERIDOSE LLC - 483S 2012
2012-7931	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Pine Rebecca K Pine	K083767
2012-7932	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Trishia Dwyer GE Healthcare	K113356
2012-7933	11/05/2012 12/04/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leola M. Anderson GERTLER LAW FIRM	K921224

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-7934	11/05/2012 12/04/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 10/1-31/2012
2012-7935	11/05/2012 12/04/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 10/1-31/2012
2012-7936	11/05/2012 12/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2012-7937	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K120543
2012-7938	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K112040
2012-7939	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Erin McCoy Tampa General Hospital	K121679
2012-7940	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K101823
2012-7941	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K103831
2012-7942	11/05/2012 12/04/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laurie Cartwright ARTHROCARE CORP	K120078
2012-7943	11/05/2012 12/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Hug Merck Consumer Care	ANDA 071739 - SBA
2012-7944	11/05/2012 12/04/2012	FDA/OF/CFSAN/OCD/EOS/	Doug Iten WFTS TV	MONSTER ENERGY DRINK - AERS (01/02/2007 - 11/01/2012)
2012-7945	11/05/2012 12/04/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Miles Frazer, Greene, Upchurch & Baker, LLC	SULFASALAZINE - AERS WARNINGS, CORR ETC
2012-7946	11/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll	K111821

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	12/04/2012		Medovations Inc.	
2012-7947	11/05/2012 12/04/2012	ORA/OCI/ ORA/OCI/	Jake Pearson Wired Magazine	GOOGLE INC ONLINE ADVERTISEMENT OF PHARMACIES - 2009 INVESTIGATION RECS
2012-7948	11/05/2012 12/04/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - EIR 05/24/2010; EIR 04/04/2008
2012-7949	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	NCT01577654, NCT01170650 - ISRs
2012-7950	11/06/2012 12/05/2012	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Mike Pagano Kraft Foods Global Inc.	KRAFT GREEN GODDESS SALAD DRESSING - SAMPLE RESULTS
2012-7951	11/06/2012 12/05/2012	FDA/OF/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	MONSTER ENERGY DRINKS - CAERS
2012-7952	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dari Darabbeigi Persyst Development Corporation	K090019, K092039, K120485 ETC
2012-7953	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202428
2012-7954	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	Mark Patterson Lila Enterprise, LLC	K111501
2012-7955	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Bruce Thompson Bruce Thompson	ISR 10482 10470 10471, ETC
2012-7956	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel Gofman SERRADO CAPITAL LLC	GASTROINTESTINAL DRUGS ADVISORY COMMITTEE TRANSCRIPT 10/16/12
2012-7957	11/06/2012	OC/OOPD/	Diane Schulman	TETRACOSACTIDE HEXAACETATE - ORPHAN DRUG

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	12/05/2012	FDA/OMPT/OSMP/OOPD/	The Indago Group Inc.	APPLICATION
2012-7958	11/06/2012	FDA/OMPT/CDER/ORP/DIDP/	Daryl Davis	BURZYNSKI RESEARCH INSTITUTE - DSI SUMMARY OF FINDINGS 08/01
	12/05/2012	FDA/OMPT/CDER/ORP/DIDP/	Davis, Daryl	
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/		
2012-7959	11/06/2012	FDA/OMPT/CDER/ORP/DIDP/	Doe J	ANASTROZOLE - AER
	12/05/2012	FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
2012-7960	11/06/2012	ORA/	JOHN L. HOLAHAN	SIMPLY THICK, WAKE COUNTY, NC; ST LOUIS, MO - SPL 656840, TEST RESULTS 6/2011
	12/05/2012	ORA/	SIMPLY THICK LLC	
		FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/		
2012-7961	11/06/2012	ORA/	MARILYNN WHITNEY	TOBACCO MFRS - EIRS, 483S AFTER 9/11
	12/05/2012	ORA/	COVINGTON BURLING LLP	
		FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/		
		FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/		
		FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/		
		FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/		
		FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/		
		FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/		
2012-7962	11/06/2012	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY	LIST OF TOBACCO PRODS FOR WHICH FDA ISSUED A SUBSTANTIAL EQUIVALENCE ORDER; SUMMARY OF ADVERSE HEALTH EFFECTS
	12/05/2012		COVINGTON & BURLING LLP	
2012-7963	11/06/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JOELLE G. NELSON	TOXIN TECHNOLOGY INC - ACTIVE PHARMACEUTICAL INGREDIENT (API) TESTING LAB
	12/05/2012		JOHANSON & FAIRLESS LLP	
2012-7964	11/06/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	SUSAN B. MILLS	E COLI OUTBREAK AT CLEVELAND CO (NC) FAIR FROM 9/27 TO 10/7/12 - INVESTIGATION RECS, SPL SUMMARIES, TRACE BACK DATA, ETC
	12/05/2012		WEINBERG WHEELER ET AL	

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2012-7965	11/06/2012 12/05/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEVIN M. DWYER, Jr. LAW OFFICE OF KEVIN M DWYER JR	HARVARD CLNCL TRIAL RESEARCH INSTITUTE 12/09 INVESTIGATION OF THE FAILURE TO REPORT A SEVERE ADVERSE EVENT (SAE)
2012-7966	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	EILEEN BOYLE HOLOGIC INC	MEDIMAPS GROUP SA - TBS INSIGHT K121716
2012-7967	11/06/2012 12/05/2012	FDA/OF/CFSAN/OCD/EOS/	WALBAUM, RICHARD	NERIUM INTL LLC - NERIUM AD AGE DEFYING TREATMENT AER 8/11 TO PRESENT
2012-7968	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	EILEEN BOYLE HOLOGIC INC	ON DIAGNOSTICS - VIRTUOST K113725
2012-7969	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/	BERRYMAN, THOMAS	UROMED PATCH K974600
2012-7970	11/06/2012 12/05/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	YVONNE M. FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	PARADIGM QUICK SET INFUSION SETS K011071 CLASS I RECALL ACTION MEMO
2012-7971	11/06/2012 12/05/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	JANUVIA - AER
2012-7972	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services, Inc.	FOI DAILY LOG 10/15-19/12
2012-7973	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 10/8-12/12
2012-7974	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services, Inc.	FOI DAILY LOG 10/22-26/12
2012-7975	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 10/1-5/12
2012-7976	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/15-19/12
2012-7977	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/22-26/12
2012-7978	11/07/2012	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 10/1-5/12

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	12/06/2012		DOMINION GROUP INC	
2012-7979	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/8-12/12
2012-7980	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/22-26/12
2012-7981	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/1-5/12
2012-7982	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/8-12/12
2012-7983	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/15-19/12
2012-7984	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/8-12/12
2012-7985	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/15-19/12
2012-7986	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/1-5/12
2012-7987	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/1-5/12
2012-7988	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/22-26/12
2012-7989	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/22-26/12
2012-7990	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/1-5/12
2012-7991	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/8-12/12
2012-7992	11/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN	FOI DAILY LOG 10/15-19/12

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	12/06/2012		WOLTERS KLUWER LAW & BUSINESS	
2012-7993	11/07/2012 12/06/2012	ORA/OCI/ ORA/OCI/	A CARIN WEINRICH SOREFF LAW	INDIVIDUAL RECS
2012-7994	11/07/2012 12/06/2012	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	PAUL W TRIPP LINCARE INC	GOLDEN SANDS RESPIRATORY CARE SERVICES INC,WI - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2012-7995	11/07/2012 12/06/2012	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LOU CAPUTO EMORD & ASSOCIATES, P.C.	BLIS TECHNOLOGIES LTD - BLIS K-12 TRAVEL GUARD IMPORT REFUSAL NOTICE OF DETENTION & HEARING
2012-7996	11/07/2012 12/06/2012	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	LESLIE SHOJI INTEREX INDUSTRIES LTD	UNITED 1 INTERNATIONAL LABS, FARMERS BRANCH, TX; CEUTICAL LABS, FARMERS BRANCH, TX; MICROCONSULT INC, CARROLLTON, TX, ETC - EIRS
2012-7997	11/07/2012 12/06/2012	FDA/OO/ FDA/OO/OHR/	JOHN SANDERS BENEFIT COORDINATORS	LIST OF FDA EMPLOYEES - SUBORDINATE ELEMENTS, AGENCIES, FIELD COMPONENTS, ETC
2012-7998	11/07/2012 12/06/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	SUSAN B MILLS WEINBERG WHEELER ET AL	CLEVELAND COUNTY (NC) FAIR - E COLI OUTBREAK EIRS, TRACE BACK DATA, SPL SUMMARIES, ETC 9/27/12-10/7/12
2012-7999	11/07/2012 12/06/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	SHANDIN KLOBE BAKER STERCHI COWDEN & RICE LLC	NEVADA HEART AND VASCULAR CENTER. LAS VEGAS, NV - PET SCANS INVESTIGATION RECS, INSP FINDINGS, CORR, ETC 1/05 TO PRESENT
2012-8000	11/07/2012 12/06/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	SHANDIN KLOBE BAKER STERCHI COWDEN & RICE LLC	NEVADA HEART AND VASCULAR CENTER (LONGFORD MEDICAL CENTER), LAS VEGAS, NV - PET SCAN INVESTIGATION RECS, CORR, VIOLATIONS, ETC 1/05 TO PRESENT
2012-8001	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	JEFFREY J JONES JONES DAY	SCOTTS MIRACLE-GRO CO - WILD BIRD FOOD PRODS RECS 1/08 TO PRESENT
2012-8002	11/07/2012 12/06/2012	CVM/OCD/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JEFFREY J JONES JONES DAY	INDIVIDUAL RECS
2012-8003	11/07/2012 12/06/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	PATTI WALLER MARLER CLARK ATTYS	TANIMURA & ANTLE INC - ROMAINE LETTUCE RECALL COMM

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		ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/		
2012-8004	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	Doe J	RULES, REGULATIONS ABOUT GLUTEN IN FOODS
2012-8005	11/07/2012 12/06/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/COS/OES/ OC/COS/OES/	LISSETTE HOWARD POCHE UNIV OF TEXAS MD ANDERSON CANCER CENTER	ROBERT E YOUNG MD - CLNCL INVESTIGATOR DISQUALIFICATION PROCEEDINGS 10/15/82
2012-8006	11/07/2012 12/06/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ALAN G MINSK ARNALL GOLDEN GREGORY LLP	BENJAMIN BIOMEDICAL INC, ST PETERSBURG, FL - EIRS, CORR 2007
2012-8007	11/07/2012 12/06/2012	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JONATHAN M RIVERA MANUEL A ROMERO PC	GOYA FOODS INC - CMLPNT
2012-8008	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDY WU UNIV OF PENNSYLVANIA WHARTON SCHOOL	ORANGE BOOK 1980 TO PRESENT
2012-8009	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Matt Daniel Prosight Capital	VINTAFOLIDE - AERS (01/01/2000 - 11/06/2012)
2012-8010	11/07/2012 12/06/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Liz Pretzinger Rawls McNelis + Mitchell	INDIVIDUAL RECS
2012-8011	11/07/2012	FDA/OMPT/CDER/GRP/DIDP/		AZITHROMYACIN - AERS (01/01/1996 - 11/06/2012)

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	12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	McNerney, Jon	
2012-8012	11/07/2012 12/06/2012	FDA/OF/CFSAN/OCD/EOS/	CAPSTONE LLC	MONSTER ENERGY DRINKS - AERS (01/01/2009 - 11/06/2012)
2012-8013	11/07/2012 12/06/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tammy Covert Simon Greenstone Panatier Bartlett, PC	TOLUENE, HYDROQUINONE IN HAIR AND NAIL PRODUCTS - CORR WITH COLOMER BEAUTY BRANDS USA, INC., CREATIVE NAIL DESIGNS, INC, LOREAL USA, ETC
2012-8014	11/07/2012 12/06/2012	FDA/OF/CFSAN/OCD/EOS/	Cdn Cosmetic Toilatry and Frag Assoc.	STUDY SUBMITTED TO FDA BY COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION - ABSORPTION, DISTRIBUTION, METABOLISM AND EXCRETION OF RED NO 9
2012-8015	11/07/2012 12/06/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K831004
2012-8016	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Mallari Regis University	CRESTOR - AERS (08/29/2003 - 11/06/2012)
2012-8017	11/07/2012 12/06/2012	FDA/OF/CFSAN/OCD/EOS/	Paulina Do EXPONENT	CAP 4C0276
2012-8018	11/07/2012 12/06/2012	FDA/OC/OES/DFOI/	FREIFELDER, JACK FRANCIS	FOI REQUESTS 9/1/12-10/1/12
2012-8019	11/07/2012 12/06/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 10/1-31/12
2012-8020	11/07/2012 12/06/2012	FDA/OMPT/CDRH/OCER/DFOI/	DARI DARABBEIGI PERSYST DEVELOPMENT CORP	NATUS MEDICAL INC - NATUS NEUROWORKS K090010; OPTIMA NEUROSCIENCE INC - IDENTEVENT K092039; MOBERG RESEARCH INC - COMPONENT NEUROMONITORING SYS K080217, ETC
2012-8021	11/07/2012 12/06/2012	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHARLES CELESTE EAS Consulting Group, LLC	NOVARTIS VACCINES & DIAGNOSTICS, EMERYVILLE, CA - 483SS 4/12 TO PRESENT
2012-8022	11/07/2012	ORA/OCI/		INDIVIDUAL RECS

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	12/06/2012	ORA/OCI/	Doe J	
2012-8023	11/08/2012	ORA/	steve caritis	COMPOUNDED MAKENA - LAB RESULTS
	12/07/2012	ORA/	UNIV OF PITTSBURGH	
		FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/		
		FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/		
2012-8024	11/08/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Robert Blaskiewicz	ANTINEOPLASTONS AS EXPERIMENTAL CANCER THERAPY - APPROVALS, WAIVERS
	12/07/2012		Self	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2012-8025	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/		K120941
	12/07/2012		HealthInterlink	
2012-8026	11/08/2012	FDA/OF/CFSAN/OCD/EOS/		ENERGY DRINKS - AERS (01/01/2010 - 11/07/2012)
	12/07/2012		Zafar Hayat Khan	
2012-8027	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	SOOJUNG MOON	K905262; K904870; K963100 ETC
	12/07/2012		ENDOTEC INC.	
2012-8028	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre	P010019
	12/07/2012		EyeReg Consulting, Inc.	
2012-8029	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/		K120941
	12/07/2012		HealthInterlink	
2012-8030	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Danna Kehm	K112858
	12/07/2012		HealthInterlink	
2012-8031	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre	K001962
	12/07/2012		EyeReg Consulting, Inc.	
2012-8032	11/08/2012	FDA/OMPT/CDRH/OCER/DFOI/		K072272

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	12/07/2012		HealthInterlink	
2012-8033	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	P980006
2012-8034	11/08/2012 12/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Parker Theuninck Meagher & Geer, PLLP	METOCLOPRAMIDE-CONTAINING PRODUCTS - NOTIFICATIONS 12/08
2012-8035	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	P040045
2012-8036	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K100349
2012-8037	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K032390
2012-8038	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andre EyeReg Consulting, Inc.	K002099
2012-8039	11/08/2012 12/07/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ASHER KASSEL LIFEWATCH TECHNOLOGIES LTD	SOTERA WIRELESS - K122036, MONEBO TECHNOLOGIES - K062282
2012-8040	11/08/2012 12/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	LTR TO CDRH OR CBER TO ANY CLNCL REGARDING LAB DEVELOPED TESTS (LTD) LAST 2 YRS
2012-8041	11/08/2012 12/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRANDON L. BOGLE LEVIN PAPANTONIO ET AL	MERCK & CO - FOSAMAX ATYPICAL FEMUR FRACTURES AERS, CLNCL TRIAL DATA
2012-8042	11/08/2012 12/07/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS WONG DEETH WILLIAMS WALL LLP	FDA APRVD DRUG PRODUCTS: WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 16TH EDITION (1996); CUMULATIVE SUPPLEMENT 1/96 TO 7/96
2012-8043	11/08/2012 12/07/2012	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	DONALD N. BLUE ZETETIC INC	ENTRY NO AV3-00379904
2012-8044	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	BROWN 219191, KENYA	JOHNSON & JOHNSON/JANSSEN PHARMA - RESPERDAL (RESPIDOL) AER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8045	11/08/2012 12/07/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY, HOMER & CHIN- CAPLAN PC	VAERS - INDIVIDUAL RECS
2012-8046	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/15-19/12
2012-8047	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/22-26/12
2012-8048	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 10/8-12/12
2012-8049	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/17-21/12
2012-8050	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/8-12/12
2012-8051	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/22-26/12
2012-8052	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 10/15-19/12
2012-8053	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/17-21/12
2012-8054	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCRAMP CanReg, Inc.	DAILY LOG 10/22-26/12
2012-8055	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 10/15-19/12
2012-8056	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 10/8-12/12
2012-8057	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 9/24-28/12

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2012-8058	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/8-12/12
2012-8059	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 10/15-19/12
2012-8060	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIE INC	DAILY LOG 10/22-26/12
2012-8061	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIE INC	DAILY LOG 10/8-12/12
2012-8062	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA WEBVIEW/FERDIE INC	DAILY LOG 10/15-19/12
2012-8063	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/24-28/12
2012-8064	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	WILLIAM A. OLSON Center for Regulatory Services, Inc.	DAILY LOG 9/24-28/12
2012-8065	11/08/2012 12/07/2012	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/17-21/12
2012-8066	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	Michaela Laussegger Austrian Trade Commission	AUSTRALIAN TRADE COMMISSION - LIST OF ESTABLISHMENTS USING AS US AGENT FOR BIOTERRORISM FOOD REGISTRATION
2012-8067	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten	INDIVIDUAL RECS
2012-8068	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	CFSAN BUDGET EXECUTION AND ANALYSIS & REPORTING TEAM MEMBERS - NAMES, DUTIES, PROJECT TIMELINES, ETC (10/01/2009 - 11/08/2012)
2012-8069	11/09/2012 12/10/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Glenn Irish Glenn Irish Consulting	SHIRE, LEXINGTON, MA - 483 (11/01/2011 - 11/08/2012)
2012-8070	11/09/2012 12/10/2012	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/NOL-	Kimberly Kindy THE WASHINGTON POST	CENTRAL ADMIXTURE PHARMACY INC, APOTHECURE, PHARMEDIUM SERVICES - INSPECTION RECS

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		DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ ORA/ ORA/		
2012-8071	11/09/2012 12/10/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	AMRI	BAXTER, MARION, NC - EIR MOST RECENT
2012-8072	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2012-8073	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	LaVeeta Moten	CORR RE GS-14 TRAVEL LEAD POSITION WITHIN CFSAN
2012-8074	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	LaVeeta Moten	OFFICE OF MANAGEMENT SYSTEMS - TRAINING RECS
2012-8075	11/09/2012 12/10/2012	ORA/ ORA/ FDA/OC/OES/DFOI/	Kimberly Kindy THE WASHINGTON POST	CENTRAL ADMIXTURE PHARMACY SERVICES, PHARMEDIUM, APOTHECURE - INSPECTION RECS
2012-8076	11/09/2012 12/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	joseph barton joseph barton	ORANGE BOOK - CORTICOTROPIN
2012-8077	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	MONSTER ENERGY DRINKS - AERS
2012-8078	11/09/2012 12/10/2012	OM/OMP/DODM/	Carrie Kahn CHEMRISK LLC	DKT 1975N-0190 - COMMENTS SUBMITTED BY THE SOCIETY OF THE PLASTICS INDUSTRY RE VINYL CHLORIDE EXPOSURE FROM CUTTING PVC PLASTIC FILM
2012-8079	11/09/2012 12/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Seongsoo Park DAEWOONG AMERICA INC	NDA 019594

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2012-8080	11/09/2012 12/10/2012	ORA/ORM/ ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG FACILITIES, ETC - 483S 10/1-31/12
2012-8081	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	FRANK E PISCITELLI JR PISCITELLI LAW FIRM	WHITE WAVE FOODS CO, BROOMFIELD, CO - HORIZON ORGANIC MILK PRODS INVESTIGATIVE RECS
2012-8082	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten	IMPAC TRAINING SESSION - PRESENTERS, TRAINING MATERIALS
2012-8083	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten	OFF ICE OF MANAGEMENT SYSTEMS - REPLACEMENT FOR DETAILS
2012-8084	11/09/2012 12/10/2012	CVM/OCD/	AVINASH KAR NATURAL RESOURCES DEFENSE COUNCIL	VOLUME OF ANTIBIOTICS USED ANNUALLY IN FOOD-PRODUCING ANIMALS - RECS 2000 TO PRESENT
2012-8085	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/ FDA/OO/OHR/	LaVeeta Moten	EDUCATION AND EXPERIENCE RECS - GOVERNMENT BUDGET
2012-8086	11/09/2012 12/10/2012	ORA/ ORA/	JUSTIN BROWNE ESQ JANET, JENNER & SUGGS, LLC	NEW ENGLAND COMPOUNDING CENTER - EIRS, 483S, TESTING RECS, ETC 10/26/12
2012-8087	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LOU CAPUTO EMORD & ASSOCIATES, P.C.	BLIS TECHNOLOGIES LTD - BLIS K-12 TRAVEL GUARD IMPORT REFUSAL NOTICE OF DETENTION & HEARING
2012-8088	11/09/2012 12/10/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SHUGART, ROBERT M	REGENERATIVE TECHNOLOGIES INC - EIR, WARNING LTR 10/12
2012-8089	11/09/2012 12/10/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BECKY COOSEMAN BROWN & CROUPPEN PC	CRONOBACTER SAKAZAKII/CRONOBACTER SP/ENTEROBACTER SAKAZAKII - CORR, TESTING RECS, DENDROGRAMS, ETC; INDIVIDUAL RECS
2012-8090	11/09/2012 12/10/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRANDON L BOGLE LEVIN PAPANTONIO THOMAS ET AL	MERCK & CO INC - FOSAMAX (ALENDRONATE SODIUM) AERS, CLNCL RECS
2012-8091	11/09/2012 12/10/2012	FDA/OC/OES/DFOI/	COLLEEN K DUCAS SANOFI PASTEUR	2012-6926
2012-8092	11/09/2012	FDA/OGROP/ORA/CE-FO/DET-	MICHAEL C SKOUTERIS	HILL-ROM COMPANY CORP, BATESVILLE, IN - DEFECTIVE

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	12/10/2012	DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SKOUTERIS & MAGEE PLLC	HOSPITAL BEDS INVESTIGATION RECS, RECALL, WARNINGS, ETC
2012-8093	11/09/2012 12/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NURIA MARCOS OLIVAN GLENMARK PHARMACEUTICALS MEXICO SA DE CV	AARTI INDUSTRIES LTD, THANE, INDIA; SYMBIOTEC PHARMALAB LTD, INDORE, INDIA; MATRIX LABORATORIES LTD, SECUNDERABAD, INDIA - EIRS, 483S
2012-8094	11/09/2012 12/10/2012	ORA/ ORA/	ANDREW KAHN DAVIS COWELL & BOWE LLP	ST JUDE MEDICAL INC, SYLMAR, CA - 483 10/12
2012-8095	11/09/2012 12/10/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	SIMILAC, ENFAMIL INFANT FORMULA ENTRY #DP406043860 - RECS
2012-8096	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL, INC.	3M - ESPE LAVA CHAIRSIDE ORAL SCANNER K073199
2012-8097	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL, INC.	3M - UNITEK LAVA CHAIRSIDE ORAL SCANNER K081961
2012-8098	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LIMIN ZHENG FISH & RICHARDSON PC	VYSIS - UROZYSION BLADDER CANCER RECURRENCE KIT K011031
2012-8099	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	LIMIN ZHENG FISH & RICHARDSON PC	ABBOTT MOLECULAR - UROVYSION BLADDER CANCER KIT P030052
2012-8100	11/09/2012 12/10/2012	OM/OMP/DODM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIE NAUD GROUPE BNA CONSULTANT GROUP	BIOLOGICAL TESTING PROCEDURES FOR FLUORIDE DENTIFRICES - DKT 1980N-0042
2012-8101	11/09/2012 12/10/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CANDICE DURRENCE OPTIMER PHARMACEUTICALS INC	OPTIMER PHARMACEUTICALS INC - DIFID (FIDAXOMICIN TABS) NDA 201-699 AERS 4/27/12-11/7/12
2012-8102	11/09/2012 12/10/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	DONNIE ALLEN SNOW SKOUTERIS & MAGEE PLLC	HILL-ROM COMPANY CORP, BATESVILLE, IN - EIRS, 483S, MDRS, ETC

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2012-8103	11/09/2012 12/10/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	HANIF SACHEDEDINA CIPHER PHARMACEUTICALS INC	AIDERAX PHARMACEUTICALS INC, CORONA, CA - EIRS, 483S MOST RECENT
2012-8104	11/09/2012 12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	ROBB PERRY NORTH AMERICAN RESCUE LLC	COMBAT MEDICAL SYSTEMS LLC - COMBAT READY CLAMP K102025
2012-8105	11/09/2012 12/10/2012	FDA/OC/OES/DFOI/	ROBERT P CHARROW GREENBERG TRAURIG LLP	2006-15538, 2006-15634, 2012-3772
2012-8106	11/13/2012 12/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ORTAV YEHUDAI GREAT POINT PARTNERS LLC	SYNCO BIO PARTNERS BV, AMSTERDAM, NETHERLANDS - 483S 1/12 TO PRESENT
2012-8107	11/13/2012 12/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ORTSV YEHUDAI GREAT POINT PARTNERS LLC	BOEHRINGER INGELHEIM AUSTRIA GMBH, VIENNA, AUSTRIA - 483S 1/12 TO PRESENT
2012-8108	11/13/2012 12/11/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAY H HENDERSON JAY HENDERSON PLLC	PARKE DAVIS - CEREBYX (FOSPHENYTOIN) NDA 20-450 LBLG OR LBLG CHANGES 1/1/07 TO 11/1/12
2012-8109	11/13/2012 12/11/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ORTAV YEHUDIA GREAT POINT PARTNERS LLC	APTUIT LLC, KANSAS CITY, MO; HARRISONVILLE, MO - 483S 1/12 TO PRESENT
2012-8110	11/13/2012 12/11/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	KEATON WALKER, TRANSPORTATION LLC - SLAUGHTER OF HORSES CORR, LICENSES, PERMITS, ETC 1/11 TO PRESENT
2012-8111	11/13/2012 12/11/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KYLA BERNNETT PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY	EASTERN EQUINE ENCEPHALITIS VACCINE - RPTS, IND, SS&E, ETC
2012-8112	11/13/2012 12/11/2012	FDA/OF/CFSAN/OCD/EOS/	CARLA R SCARMAZZI KING & SPALDING	HUMAN EXPOSURE TO CAFFEINE - RESP LTR 8/10/12
2012-8113	11/13/2012 01/09/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ ORA/ ORA/	SCHRIFLER, JEFF	CDER OR CDRH FOREIGN INSP RECS

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2012-8114	11/13/2012 12/11/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ELIZBETH RICHARDS LATHAM & WATKINS LLP	EXCLUSIVE SUPPLEMENTS - BIORHYTHM SSIN JUICE; FAHRENHEIT NUTRITION - LEAN EFX; GASPARI NUTRITION - SPIRODEX, ETC RESP TO WARNING LTRS 4/24/12
2012-8115	11/13/2012 12/11/2012	FDA/OC/OES/DFOI/	DUCHNESKIE, STEPHANIE	LIST OF RECS REQUESTED BY PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS (PETA) 9/1/12 TO 10/1/12
2012-8116	11/13/2012 12/11/2012	ORA/ORM/ ORA/ORM/	TYLR KENYON NORTHCOAST RESEARCH	LIST OF EIRS, 483S - LAST SIX MONTHS
2012-8117	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, SMOKELESS TOBACCO COMPANY LLC - LIST OF PRODUCTS NOTIFIED FDA
2012-8118	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ALTRIA CLIENT SERVICES, PHILIP MORRIS USA INC, SMOKELESS TOBACCO COMPANY LLC - PRODUCT LISTING
2012-8119	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	QUARTERLY CTP USER FEES 10/01/11 TO PRESENT
2012-8120	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	CTP USER FEES SINCE 10/01/11
2012-8121	11/14/2012 12/12/2012	FDA/OMPT/CTP/OD/ OC/OM/OFM/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	CTP USER FEES - MANUFACTURERS AND IMPORTERS ASSESSED 10/01/11 TO PRESENT
2012-8122	11/14/2012 12/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christine Phillips, PhD, RAC ELI LILLY & CO	BLA 125276 S49
2012-8123	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	MONSTER ENERGY - AERS
2012-8124	11/14/2012 12/12/2012	CVM/OCD/	Mary Schwager News Pro Net TV	PET MEDICATIONS ERRORS - LAST THREE YEARS
2012-8125	11/14/2012 12/12/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RON BELLDEGRUN belldegrun, ron	NDA 021610 - ABUK IMPURITY

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8126	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Phillips, PhD, RAC Eli Lilly and Company, Inc.	NDA 203214
2012-8127	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Ryan Gregerson American Sleep Association	K963591
2012-8128	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	RED BULL - AERS
2012-8129	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	ROCKSTAR ENERGY PRODUCTS - AERS
2012-8130	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Geoffrey Robert Chambers Geoffrey R Chambers	VASCEPA EXCLUSIVITY DETERMINATION LETTER
2012-8131	11/14/2012 12/12/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	VISIUM FUNDS	IMMUCOR - NOTICE OF INTENT TO REVOKE; INSPECTION RECS
2012-8132	11/14/2012 12/12/2012	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	CARDINAL HEALTH	ANAZAOHEALTH CORP, TAMPA, FL - 483 (12/1/2009 - 12/23/2009)
2012-8133	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Anello DILWORTH PAXSON LLP	OXYCONTIN - AERS
2012-8134	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braido EdgeOne Medical Inc	ABCO DEALERS, INC - GUAGE SPONGE X-RAY DETECTABLE X-RAY 510(K) NOTIFICATION
2012-8135	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braido EdgeOne Medical Inc	K071519
2012-8136	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braido EdgeOne Medical Inc	K821150

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2012-8137	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	UC-Care	K120187
2012-8138	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braido EdgeOne Medical Inc	K082703
2012-8139	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braido EdgeOne Medical Inc	K103641
2012-8140	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joe Braido EdgeOne Medical Inc	K103641
2012-8141	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	UC-Care	K122329
2012-8142	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	UC-Care	K081093
2012-8143	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Merridee Wouters Deakin University	APPROVED DRUGS - LISTING
2012-8144	11/14/2012 12/12/2012	ORA/OE/ ORA/OE/	Oliver Yu Zymergi LLC	INSPECTION SPREADSHEET - UPDATE 03/30/2012 - 11/06/2012
2012-8145	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	Stephen Teti Scott+Scott, LLP	VIROPHARMA - CORR RE CITIZENS PETITIONS
2012-8146	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K950034
2012-8147	11/14/2012 12/12/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PATRICIA MURPHY - 483, EIR, CORR
2012-8148	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K880047
2012-8149	11/14/2012 12/12/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING &	DARIN S WIEGERS - EIR, 483, CORR

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SUBMISSIONS				
2012-8150	11/14/2012 12/12/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Veronica Vogt Vogt, Veronica	ENBREL - COMPLAINTS, AERS, WARNINGS ETC
2012-8151	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Elisa D. Harvey, DVM, PhD CardioMed Device Consultants, LLC	K121083
2012-8152	11/14/2012 12/12/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Paula A. Berezansky Diamond Pharmacy Services	SHAMROCK MEDICAL SOLUTIONS GROUP LLC - INSPECTIONS, VIOLATIONS, WARNING LETTER RECS, ETC
2012-8153	11/14/2012 12/12/2012	CVM/OCD/	Aeree Lee Stason Pharmaceuticals, Inc.	ZHEJIANG JINHUA CONBA BIOPHARM CO - EIR (03/15/2010 - 03/19/2010)
2012-8154	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	ABBOTT LIQUID PROTEIN FORTIFIER - PREMARKET NOTIFICATIONS, CORR
2012-8155	11/14/2012 12/12/2012	FDA/OO/OFBA/OAGS/	Linda Ulrich - FDA Linda.Ulrich@fda.hhs.gov CHILDREN'S NATIONAL MEDICAL CENTER	PEDIATRIC DEVICE CONSORTIA GRANT - SUCCESSFUL GRANT APPLICATIONS RFA-FD-11-002
2012-8156	11/14/2012 12/12/2012	CVM/OCD/ ORA/ ORA/ ORA/OCI/ ORA/OCI/ ORA/OE/ ORA/OE/	ALEX R LUMAGHI DOWD & DOWD PC	SCOTTS CO LLC - MIRACLE GRO MORNING SONG WILD BIRD SEED USE OF STORCIDE II AND ACTELIC 2E RECS
2012-8157	11/14/2012 12/12/2012	FDA/OC/OES/DFOI/	KASP 44179-424, GEORGE	OPERATION TRIPLE THREAT - POLICY RECS; INDIVIDUAL RECS
2012-8158	11/14/2012 12/12/2012	FDA/OC/OES/	JENNIFER HSIEH HEALTHCARE RESEARCH CONSULTING GROUP	GILEAD SCIENCES MTG - ISSUES OF MUTIAL INTEREST EMAILS 8/6/12
2012-8159	11/14/2012 12/12/2012	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 9/1-30/12
2012-8160	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	RED BULL - CAERS 2004 TO 11/12/12

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2012-8161	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	FIVE HOUR ENERGY - CAERS 2004 TO 11/12/12
2012-8162	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	ROCKSTAR - CAERS 2004 TO 11/12/12
2012-8163	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	NOS - CAERS 2004 TO 11/12/12
2012-8164	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	AMP - CAERS 2004 TO 11/12/12
2012-8165	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	REDLINE - CAERS 2004 TO 11/12/12
2012-8166	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	FULL THROTTLE - CAERS 2004 TO 11/12/12
2012-8167	11/14/2012 12/12/2012	FDA/OF/CFSAN/OCD/EOS/	OSTERHOLM, MICHAEL T	LEAFY GREEN PRODS - LISTERIA MONOSYTOGENES INVESTIGATION RECS
2012-8168	11/14/2012 12/12/2012	FDA/OMPT/CDRH/OCER/DFOI/	Samantha K. Sledd Hall & Sethi, PLC	K042800
2012-8169	11/15/2012 12/13/2012	FDA/OC/OES/DFOI/	LaVeeta Moten	INDIVIDUAL RECS
2012-8170	11/15/2012 04/12/2013	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten	OVERTIME AND COMPENSATORY TIME PAID TO OFFICE OF MANAGEMENT SYSTEMS (10/01/2009 - 11/08/2012)
2012-8171	11/15/2012 12/13/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Doe J	PINES INTERNATIONAL, INC, LAWRENCE, KS - 483, DETERMINATIONS, ETC
2012-8172	11/15/2012 12/13/2012	OM/OMP/DODM/	Doe J	INDIVIDUAL RECS
2012-8173	11/15/2012 12/13/2012	CVM/OCD/	Pamela Boner PFIZER ANIMAL HEALTH	NADA 135468
2012-8174	11/15/2012 12/13/2012	CVM/OCD/	Pamela Boner PFIZER ANIMAL HEALTH	NADA 9467
2012-8175	11/15/2012 01/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Mary Lynn The Windward Company	HMS VETERINARY DEVELOPMENT, TULARE, CA - EIR (02/12 - 05/12)
2012-8176	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Eden M Venti Incyte Corporation	INCYTE, WILMINGTON, DE - EIR (08/15/2011 - 08/19/2011)

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2012-8177	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	Austin McElroy Austin McElroy	K101239
2012-8178	11/15/2012 12/13/2012	OM/OMP/DODM/	Corinne Cohen Abiomed, Inc.	CIRCULATORY SYSTEMS DEVICES PANEL - TRANSCRIPTS 08/21/95
2012-8179	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Zeitler Emily Zeitler	DATA SUBMITTED TO FDA FROM MANUFACTURERS IN SUPPORT OF ANDAS FOR GENERIC CLOPIDOGREL
2012-8180	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Yuwei Zhu VANDERBILT UNIVERSITY	INFLUENZA VIRUS VACCINE, TRIVALENT, TYPES A AND B INITIAL LOT RELEASE DATES 2006-2012
2012-8181	11/15/2012 12/13/2012	FDA/OF/CFSAN/OCD/EOS/	Cristy Jones jones, cristy j	BARE ESSENTIALS, BARE MINERALS, SEPHORA - CAERS
2012-8182	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 077742 - TENTATIVE APPROVAL LETTER 11/02/2012
2012-8183	11/15/2012 12/13/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA DAILY LOG 07/16-20/2012
2012-8184	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Austin McElroy Austin McElroy	K081808
2012-8185	11/15/2012 01/16/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	none	NOVARTIS VACCINE, EMERYVILLE, CA - EIR, 483, WARNING LETTER, ETC
2012-8186	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - EIR, RESP LTR, CORR 2/12 TO 3/12
2012-8187	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - 483, RESP LTR, CORR 2/12 TO 3/12
2012-8188	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	FERCY PERSONAL CARE PRODUCTS, ZHEJIANG, CHINA - EIR, RESP LTR, CORR 3/12
2012-8189	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION	FERCY PERSONAL CARE PRODUCTS, ZHEJIANG, CHINA - 483S, RESP LTR, CORR 3/12

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SOURCE	
2012-8190	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	PRINCE MEDICAL, ERCUIS, FRANCE - EIR, RESP LTR, CORR 3/12
2012-8191	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	PRINCE MEDICAL, ERCUIS, FRANCE - 483, RESP LTR, CORR 3/12
2012-8192	11/15/2012 02/07/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	SUSAN B MILLS WEINBERG WHEELER ET AL	WEGMANS FOOD MARKETS INC, MONROE, NIAGARA, STEUBEN COUNTIES, NY, ETC - ORGANIC SPINACH & SPRING MIX BLEND E COLI OUTBREAK
2012-8193	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	MIR-COM PRODUCTS, CENTRAL CITY, PA - EIR, RESP LTR, CORR 6/12
2012-8194	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	HEMOFARM A D, VRSAC, SERBIA - EIR, RESP LTR, CORR 11/11
2012-8195	11/15/2012 12/13/2012	ORA/ ORA/ FDA/OF/CFSAN/OCD/EOS/	CLAIRE KALTENBACH CHILDRESS AHLHEIM CARY LLC	MULTISTATE ROMAINE LETTUC E COLI OUTBREAK - INVESTIGATION RECS 2011
2012-8196	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERI BATTERSHELL WASHINGTON INFORMATION SOURCE	HEMOFARM AD, VRSAC, SERBIA - 483, RESP LTR, CORR 11/11
2012-8197	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ZHONGNUO PHARMS, SHIJIAZHUANG, CHINA - EIR, RESP LTR, CORR 2011 TO 2012
2012-8198	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GENENTECH - ERIVEDGE (VISMODEGIB) NDA 203-388 SBA, RVWS, LBLG, ETC

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2012-8199	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERI BATTERSHELL WASHINGTON INFORMATION SOURCE	ZHONGNUO PHARMACEUTICALS, SHIJIAZHUANG, CHINA - 483, RESP LTR, CORR 2012
2012-8200	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ERCROS SA, MADRID, SPAIN - EIR, RESP LTR, CORR 7/11
2012-8201	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	ERCROS SA, MADRID, SPAIN - 483, RESP LTR, CORR 7/11
2012-8202	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	ASTRAZENECA LP - BRILINTA (TICAGRELOR) NDA 22-433 SBA, RVWS, LBLG, ETC
2012-8203	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SIEMENS HEALTHCARE DIAGNOSTICS, NEWARK, DE - 483, RESP LTR, CORR 12/11
2012-8204	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SIEMENS HEALTHCARE DIAGNOSTICS, NEWARK, DE - EIR, RESP LTR, CORR 12/11
2012-8205	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	VANCOMYCIN HCL CAPS - APRVL LTR 12/21/11
2012-8206	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	NEUROTHERM INC, WILMINGTON, MA - EIR, RESP LTR, CORR 4/12
2012-8207	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	NEUROTHERM INC, WILMINGTON, MA - 483, RESP LTR, CORR 4/12
2012-8208	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN-	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CENTER FOR THE IMPROVEMENT OF HUMAN FUCTIONING INTERNATIONAL, NEW YORK, NY - EIR, RESP LTR, CORR 7/11

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		DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8209	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CENTER FOR THE IMPROVEMENT OF HUMAN FUNCTIONING INTERNATIONAL, NEW YORK, NY - 483, RESP LTR, CORR 7/11
2012-8210	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRIBATTERSHELL WASHINGTON INFORMATION SOURCE	A NELSON & CO LTD, LONDON, UK - EIR, RESP LTR, CORR 11/11
2012-8211	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	A NELSON & CO LTD, LONDON, UK - 483, RESP LTR, CORR 11/11
2012-8212	11/15/2012 12/13/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - EIR, RESP LTR, CORR 11/11 TO 12/11
2012-8213	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	EILEEN DANNEMANN NATIONAL COALITION OF ORGANIZED WOMEN	MONOVALENT H1N1 INFLUENZA VAERS
2012-8214	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW#5027281
2012-8215	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	MIR-COM PRODUCTS, CENTRAL CITY, PA - 483, RESP LTRS, CORR 6/12
2012-8216	11/15/2012 12/13/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - EIR, RESP LTRS, CORR 1/12 TO 3/12

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2012-8217	11/15/2012 12/13/2012	OC/OM/OFM/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	LIST OF PAYMENTS TO FDA PURSUANT TO PRESCRIPTION DRUG USERS FEE ACT
2012-8218	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	RESOLUTION CHEMICALS, STEVENAGE, UK - EIR 01/11
2012-8219	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Green / Alex Nussbaum at Healthcor HEALTHCOR MANAGEMENT LP	MAP PHARMACEUTICALS - COMPLETE RESPONSE LETTER RE LEVADEX, CORR, 483
2012-8220	11/15/2012 12/13/2012	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Theresa Appelbaum Padberg, Corrigan & Appelbaum	MEDRAD AVANTA FLUID MANAGEMENT INJECTION SYSTEM - INVESTIGATIONS, WARNING LETTERS, RECALLS, ETC
2012-8221	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA125276, NDA22383, NDA22433, ETC - RISK EVALUATION AND MITIGATION STRATEGY ASSESSMENTS
2012-8222	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7361599, 7364893 - DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS
2012-8223	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7287296, 8227773, 8337499, 8374156 - DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS
2012-8224	11/15/2012 12/13/2012	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - 483, RESP LTRS, CORR 1/12 TO 3/12
2012-8225	11/15/2012 12/13/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION	CELLTEX THERAPEUTICS CORP, SUGARLAND, TX - EIR, RESP LTRS, CORR 4/12

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		FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	SOURCE	
2012-8226	11/15/2012 12/13/2012	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	CELLTEX THERAPEUTICS CORP, SUGARLAND, TX - 483, RESP LTRS, CORR 4/12
2012-8227	11/15/2012 12/13/2012	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - 483 11/11 TO 12/11
2012-8228	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LEISEGANG FEINMECHANIK-OPTIK, BERLIN, GERMANY - EIR 4/12
2012-8229	11/15/2012 12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	LEISEGANG FEINMECHANIK OPTIK, BERLIN, GERMANY - 483 4/12
2012-8230	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SPINEFRONTIER INC, BEVERLY, MA - EIR 5/12 TO 7/12
2012-8231	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SPINEFRONTIER INC, BEVERLEY, MA - 5/12 TO 7/12
2012-8232	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR. MARCY L'ETOILE, FRANCE - EIR 3/12 TO 4/12
2012-8233	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR, MARCY I'ETOILE, FRANCE - 483 3/12 to 4/12
2012-8234	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR LTD, TORONTO, CANADA - EIR 4/12
2012-8235	11/15/2012 12/13/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHERRI BATTERSHELL WASHINGTON INFORMATION SOURCE	SANOFI PASTEUR LTD, TORONTO, CANADA - 483 4/12

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2012-8236	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ZIV HAREL ST MICHAELS HOSPITAL	PRADAXA VERSUS WARFARIN - AER
2012-8237	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADRIENNE E. FAERBER, PhD DARTMOUTH INSTITUTE	POMOTIONAL MATERIALS FOR ZYRTEC
2012-8238	11/15/2012 12/13/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ROBIN WINCHESTER KESSLERTOPAZ MELTZERCHECK LLP	ABIOMED INC - EIRS, WARNING LTRS, CORR 1/28/10, 6/10/11, 4/12, ETC
2012-8239	11/15/2012 12/13/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SUSAN B. MILLS WEINBERG WHEELER ET AL	CIRCLE G RANCH WILD ANIMAL PARK & CAMEL SAFARI, STRAWBERRY PLAINS, TN - E COLI OUTBREAK CLEVELAND COUNTY FAIR, NC
2012-8240	11/15/2012 12/13/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT M. DISOGRA, Au.D., FAAA AUDIOLOGY ASSOCIATES OF FREEHOLD PC	EAR PERFECT - INGREDIENTS
2012-8241	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sheetal Pandya TekTeam LLC.	K071364
2012-8242	11/16/2012 12/14/2012	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Holmes, Warren	ECULIZUMAB FOR THE TREATMENT OF IDIOPATHIC MEMBRANOUS GLOMERULAR NEPHROPATHY - ORPHAN DRUG DESIGNATION
2012-8243	11/16/2012 12/14/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP RECS COLLECTED FROM STATE HEALTH DEPARTMENTS ON ADVERSE EVENTS RE E-CIGARETTES
2012-8244	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marta Arcabell Laboratorios Lesvi, S.L.	INTERNATIONAL PHARMECEUTICAL RESEARCH CENTER, AMMAN, JORDAN - LAST TWO 483S
2012-8245	11/16/2012	FDA/OMPT/CDER/GRP/DIDP/	Matt Prokopczyk	SIMVASTATIN TABLETS USP - HEALTH HAZARD

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	12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR. REDDY'S LABORATORIES INC	EVALUATION
2012-8246	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Sheetal Pandya TekTeam LLC.	K001284
2012-8247	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DDD Ltd	VIPOR CHEMICALS LTD, INDIA - 483 (12/01/2006 - 12/31/2006)
2012-8248	11/16/2012 12/20/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ OM/OSS/OPILS/FDAHO/	Henry Gluckstern HENRY GLUCKSTERN	ORAL POLIO VACCINE - TEST RESULTS (01/01/1960 - 12/31/1999)
2012-8249	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CORRENS, DOERTE	SEPARATE RPTS OF ADVERSE SIDE EFFECTS 2000 TO PRESENT
2012-8250	11/16/2012 12/14/2012	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	JAMES A LOCHRIDGE PREIS & ROY	KIRKMAN GROUP INC, KIRKMAN LABS - STEVIA SWEVIA, LIQUID ZINC LAB ANALYSIS 1/10
2012-8251	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	PETER T ANDERSON ESQ ASHCRAFT & GEREL LLP	K030497
2012-8252	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHAPIRO, JOEL	DR BURZYNSKI, BURZYNSKI RESEARCH INSTITUTE (BRI) - NOTIFICATION LTR
2012-8253	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHLEEN KOONS DJA GLOBAL PHARMACEUTICALS INC	SUBOXONE FILM NDA 22-410 - SBA
2012-8254	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-7560
2012-8255	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	DARREN BROWN PROVOST UMPHREY LAW FIRM	DR ERIC WILHELMSSEN, WILHELMSSEN CONSULTING - INGREDIENT DECLARATION FOR VARIOUS SWEETNERS FDA GUIDANCE LTR 5/8/2000
2012-8256	11/16/2012	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ	DR MED KURT LOBODASCH SURGICAL MESH LTR 8/3/12

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	12/14/2012		BUTLER SNOW ET AL	(CERTIFIED)
2012-8257	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK A DAWSON COOPER FIRM	EPIPEN EPINEPHRINE INJECTOR PEN - LBLG, EXPIRATION DATE
2012-8258	11/16/2012 12/14/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIN E SEDER VENABLE LLP	INTERNEURON PHARMACEUTICALS INC - IND APPLS 1990 TO 2000
2012-8259	11/16/2012 12/14/2012	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	DIANA R MARTINI VITAL THERAPIES	DR RAJULI PATEL, MARICOPA INTEGRATED HEALTH SYSTEM - 483 8/13/03
2012-8260	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Tony Collins-Kwong ALLINA HEALTH SYSTEM	PHARMEDIUM - 483S (01/01/2007 - 11/14/2012)
2012-8261	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	CAITLIN CAREY MINER HARE WYNN NEWELL & NEWTON LLP	AMERICAN MEDICAL SYSTEMS INC - SURGICAL MESH RPTS
2012-8262	11/16/2012 12/14/2012	FDA/OF/CFSAN/OCD/EOS/	JORDAN #B24482, VALDEZ	SOYA, SOYBEAN - CAERS, STUDIES, MEMOS, ETC
2012-8263	11/16/2012 03/11/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	LARRY R ROGERS POWER ROGERS & SMITH PC	CYBERONICS MODEL 102 23437, MODEL 103 SN 19766 - INVESTIGATION, STUDIES, TEST MATERIALS, ETC
2012-8264	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/29/12-11/2/12
2012-8265	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 10/22-26/12
2012-8266	11/16/2012 12/14/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	JOHN LYONS John Lyons	5-HOUR ENERGY, MONSTER ENERGY, VITAMIN WATER, ETC - AERS (11/01/2007 - 11/15/2012)
2012-8267	11/16/2012 12/14/2012	OM/OMP/DODM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2010-N-0568 - COMMENTS NOT AVAILABLE ON REGULATIONS.GOV
2012-8268	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joy Frestedt FRESTEDT INCORPORATED	K112342

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2012-8269	11/16/2012 12/14/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	elizabeth matovinovic matovinovic, elizabeth	ADVATE - AERS 07/15/03 TO PRESENT
2012-8270	11/16/2012 12/14/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	ROBERT MOSIER HODES MILMAN LIEBECK MOSIER, LLP	GRANUFLO AND NATURALYTE DRY ACID CONCENTRATE - RECALL RECS
2012-8271	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - CORR RE 02/24/12 MTG
2012-8272	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - FOLLOW UP TO WARNING LETTER (04/12)
2012-8273	11/16/2012 12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - ALL CORR RE IMPELLA CLAIMS, PROMOTIONS, MARKETING, ETC (01/12/2009 - 11/15/2012)
2012-8274	11/16/2012 12/14/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	CTP REPORT RE MENTHOL CIGARETTES
2012-8275	11/16/2012 12/14/2012	FDA/OC/OES/DFOI/	Reed Kathrein HAGENS BERMAN SOBOL SHAPIRO LLP	ABIOMED - RECS RELEASED UNDER FOIA IN 2012
2012-8276	11/19/2012 12/17/2012	FDA/OF/CFSAN/OCD/EOS/	Peter Hsu Peter Hsu	CAERS REPORTS 139012, 139013
2012-8277	11/19/2012 12/17/2012	FDA/OF/CFSAN/OCD/EOS/	Scott, Michael	FCN 899, FCN 915 - SAFETY EVALUATION
2012-8278	11/19/2012 12/17/2012	ORA/ ORA/	Tom Burton WALL STREET JOURNAL	AMERIDOSE LLC, NEW ENGLANG COMPOUNDING CENTER - ORA RECS (01/03/2005 - 10/01/2012)
2012-8279	11/19/2012 12/17/2012	FDA/OC/OES/DFOI/	MADHU SONI SONI & ASSOCIATES INC	MONSTER ENERGY DRINKS - CAERS 1/12 TO PRESENT

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2012-8280	11/19/2012 12/17/2012	FDA/OC/OES/DFOI/	RACHEL A AVAN LABATON SUCHAROW	MONSTER BEVERAGE CORP HANSEN NATURAL CORP) - ENERGY DRINKS CAERS
2012-8281	11/19/2012 12/17/2012	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOTAL NUMBER OF ORDERS OF SUBSTANTIAL EQUIVALENCE ISSUED UNDER FAMILY SMOKING PREVENTION AND TOBACCO ACT 09/01/12 TO 10/31/12
2012-8282	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	ICAD - SECONDLOOK CAD SYS P010038/S013 USER MANUAL LBLG, SS&E
2012-8283	11/19/2012 12/17/2012	FDA/OF/CFSAN/OCD/EOS/	Michelle Minton The Competitive Enterprise Institute	CAERS - ALL FOOD AND DRINK PRODUCTS LAST FIVE YEARS
2012-8284	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jake Nachmani, Esq. MORELLI RATNER PC	RISPERDAL - OFF-LABEL MARKETING RECS
2012-8285	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	VUCOMP- MULTIPLE DIGITAL MANNOGRAPHY SYS P100005/S001 MANUAL, LBLG, SS&E
2012-8286	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Koerner Ineos Barex	DMF 2343
2012-8287	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Seongsoo Park DAEWOONG AMERICA INC	NDA019594 - MEDICAL RVW, CLINICAL TRIALS
2012-8288	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kristan Phillips MacroGenics	DR YUNG-JUE BANK, SEOUL NATIONAL UNIVERISTY HOSPITAL, SEOUL, KOREA - EIR, 483 05/27/2011
2012-8289	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 201739
2012-8290	11/19/2012 12/17/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 090358

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8291	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K110753
2012-8292	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K101612
2012-8293	11/19/2012 12/17/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Hannah Cheng MASSACHUSETTS INSTITUTE OF TECHNOLOGY	PIG WHIPWORMS - SUBMISSIONS PRIOR TO 2011
2012-8294	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Wavrek Mark Wavrek	ACCUTANE - AERS
2012-8295	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Nuez / David Appleby, Esq. Hickey Law Firm	INDIVIDUAL RECS
2012-8296	11/19/2012 12/17/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Debra Sweitzer Kythera Biopharmaceuticals, Inc	AMRI, RENSSELAER, NY - EIR (01/01/2006 - 11/16/2012)
2012-8297	11/19/2012 12/17/2012	CVM/OCD/	Rachel Johnson FOI Services, Inc.	NADA 97222, NADA 108114 - SUPPLEMENTS
2012-8298	11/19/2012 12/17/2012	CVM/OCD/	Algal Scientific Corporation	GRAS APPLICATIONS FOR YEAST OR MUSHROOM-DERIVED BETA GLUCAN PRODUCTS FOR USE AS ANIMAL FEED
2012-8299	11/19/2012 12/17/2012	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Myron Levin FAIRWARNING	REVECOMED INTERNATIONAL, FULLERTON, CA; ADVANCED AESTHETIC CONCEPTS, FORT WORTH, TX - EIR, 483, WARNING LETTER (07/01/2012 - 11/16/2012)
2012-8300	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 203214
2012-8301	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125276 S049

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8302	11/19/2012 12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDANT LIVING AIDS	AMERIGLIDE, HANDICARE ACCESIBILITY, MAC LIFTGATE INC, ETC - WHEELCHAIR ELEVATORS MARKETED IN THE US NOT COMPLYING WITH FOOD DRUG & COSMETIC ACT & 21 CFR PART 800 TRADE CMPLNT INTERNAL OR EXTERNAL RECS, CORR, MAIL, ETC
2012-8303	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	THOMAS CLUDERAY ENVIRONMENTAL WORKING GROUP	SUNSCREENS - CMPLNTS, AERS, CORR 1/08 TO PRESENT
2012-8304	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES F JOHNS STEPTOE & JOHNSON	HYDROCODONE - FAERS RPTS, CMPLNTS, QUESTIONAIRES, ETC
2012-8305	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA BOGERT BOGERT, PATRICIA	TRELSTAR - TRIPTORELINE AERS
2012-8306	11/19/2012 12/17/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	AUUVI-Q NDA 201-739 - SBA
2012-8307	11/19/2012 12/17/2012	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KYLE SMITH NEEDLE SPECIALTY PRODUCTS CORP	NEEDLE SPECIALTY PRODUCTS CORP, BOYLE, MS - EIR 07/07/09
2012-8308	11/19/2012 12/17/2012	ORA/ORM/ ORA/ORM/	KIM C CAPONE PORZIO LIFE SCIENCES	LIST OF ALL INSP PURSUANT TO THE PRESCRIPTION DRUG MARKETING ACT (PDMA) 1/07 TO PRESENT
2012-8309	11/20/2012 12/18/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WAYNE GAJADHAR TROPICAL MARINE LTD	ENTRY NO AMG-0093132-3 LAB RPTS
2012-8310	11/20/2012 12/18/2012	FDA/OF/CFSAN/OCD/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services, Inc.	NYLON MXD-6 RESINS (CAS REGISTRY NO 25718-70-1) PETITIONS
2012-8311	11/20/2012	ORA/	CLAUDIA HORNBACK	GOLDEN STAR WHOLESALE INC - ENTRY NO G1710147845

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	12/19/2012	ORA/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ROANOKE TRADE SERVICES INC	REFUSAL, REDELIVERY
2012-8312	11/20/2012 12/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	BRIAN BELL BOSTON SCIENTIFIC CORP	TABLE OF MDRS AND PATIENT PROBLEM CODES 2006 TO PRESENT
2012-8313	11/20/2012 12/18/2012	FDA/OMPT/CDRH/OCER/DFOI/	HIROHIKO MURASE NSK AMERICA CORP	NSK AMERICA CORP, HOFFMAN ESTATES, IL - K052700
2012-8314	11/20/2012 12/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	PABLO PERHACS JD, PhD SEARCY DENNEY ET AL	TEVA PHARMACEUTICALS - PROPOFOL INJECTABLE EMULSION TESTING & ANALYSIS 2005 TO 2009
2012-8315	11/20/2012 12/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PABLO PERHACS, JD Ph.D SEARCY DENNEY ET AL	TEVA PHARMACEUTICALS - PROPOFOL INJECTABLE EMULSION ANDA
2012-8316	11/20/2012 12/18/2012	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PABLO PERHACS JD, Ph.D. SEARCY DENNEY ET AL	TEVA PHARMACEUTICALS - PROPOFOL INJECTABLE EMULSION EIR, 483, CO RESP, CORR 1/05 TO PRESENT
2012-8317	11/20/2012 12/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DISSELKAMP, ROBERT S	LAMICTAL - AERS 2007 TO PRESENT
2012-8318	11/20/2012 12/18/2012	FDA/OF/CFSAN/OCDE/EOS/	JOHN DOHERTY IOVATE HEALTH SCIENCES INTERNATIONAL INC	FORTHANE, HEMORUSH, FASTIN, ETC - AERS
2012-8319	11/20/2012 12/18/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125057 S0232

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2012-8320	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	ICAD - SECONDLOOK CAD SYS P010038/S013 USER MANUAL, LBLG, SS&E
2012-8321	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALEXANDER FILATOV PARASCRIPT LLC	VUCOMP - MULTIPLE DIGITAL MAMMOGRAPHY SYS P100005/S001 USER MANUAL, LBLG, SS&E
2012-8322	11/21/2012 12/19/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	CHOCOLATES - ENTRY SMLU3185964A PHOTOGRAGHS, OASIS SCREEN SHOTS, CBP FORM 3461
2012-8323	11/21/2012 12/19/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DONALD N BLUE ZETETIC	ENTRY D82-21238636 - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2012-8324	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	THEO EMISON EMISON HULLVERSON LLP	DR MICHAEL DAKE, STANFORD UNIVERSITY - CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY IN THE USA COMM, INVESTIGATIONS, RPTS, ETC
2012-8325	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	VICINO, WILLIAM	TOPOTECAN - AERS
2012-8326	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COX, JAMES E	DOMPERIDONE - AERS
2012-8327	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/CE-FO/BLT-	CHARLES SEIFE NEW YORK UNIV ARTS & SCIENCE	FABRICATED REC IN CLNCL TRIALS MUNNI SELAGAMSETTY 2/2/10, GHANDI SAADEH 12/08/08, HOWARD, MARKER 4/28/08, ETC - EIRS, 483S

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		DO/BLT-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/		
2012-8328	11/21/2012 12/19/2012	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KYLE SMITH NEEDLE SPECIALTY PRODUCTS CORP	NEEDLE SPECILTY PRODUCTS CORP, BOYLE, MS - EIR 7/07/09
2012-8329	11/21/2012 12/19/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ONA SCANDURRA COUNTRY LIFE LLC	RESP TO 483 1/10/12
2012-8330	11/21/2012 12/19/2012	ORA/ ORA/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	ANTONIO MERCANTE DELIZIA FOODS INC	CHOCOLATE HAZELNUT SPREAD - RESULTS
2012-8331	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/OIP/	GARDINER HARRIS NEW YORK TIMES	SPICE FARMS, INDIA - PROFILE RECS, NOTES, SUMMARIES, WARNING LTRS, ETC
2012-8332	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	MONSANTO - ETHOXYQUIN FAP 00001
2012-8333	11/21/2012 12/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	ZOSTAVAX - VAERS
2012-8334	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	NESTLE USA, KRAFT FOODS, JM SMUCKERS - CAERS (11/01/2010 - 10/31/2012)
2012-8335	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	COCA COLA COMPANY, PEPSICO - CAERS (11/01/2011 - 10/31/2012)
2012-8336	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	Patrick Moriarty HEALTHCOR MANAGEMENT LP	RELISTOR - AERS; FOIA REQUESTS
2012-8337	11/21/2012 12/19/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary J. McGarity Gary J. McGarity, PharmD	LUNESTA - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8338	11/21/2012 12/19/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Christine Ringler Esdaile, Barrett, Jacobs & Mone	INDIVIDUAL RECS
2012-8339	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Franck STRYKER INSTRUMENTS	K081047
2012-8340	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Andrew Han VISIUM FUNDS	INVACARE, ELYRIA, OH - 483 (01/01/2012 - 12/19/2012)
2012-8341	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Lewis ACROMED CORP	SHOW FOR CLINICAL TRIAL PARTICIPANTS - INVESTIGATION RECS
2012-8342	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/	Michelle R. Minton The Competitive Enterprise Institute	GORTON'S CRUNCHY BREADED FISH STICKS, GENERAL FOODS POP ROCKS, HERSHEY'S PAYDAY, ETC - CAERS (01/01/10-01/01/12)
2012-8343	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Ross Brooks Sanford Heisler, LLP	DEPUY ORTHOPAEDICS, INC ASR XL ACETABULAR HIP- REPLACEMENT SYSTEM - COMMUNICATIONS BETWEEN FDA AND DEPUY (10/07 TO 10/11)
2012-8344	11/21/2012 12/19/2012	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OF/CFSAN/OCD/EOS/	Mary Clare Jalonick THE ASSOCIATED PRESS	MARTE RICOTTA SALATA FRESCOLINA CHEESE - RECALL RECS, INSPECTIONS
2012-8345	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/	John Shoemaker Visium	5 HOUR ENERGY - ADVERTISING INQUIRY
2012-8346	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Tyler Kenyon NORTHCOAST RESEARCH	STRYKER INSTRUMENTS, PORTAGE, MI - 483 (6/18/2012); STRYKER MEDICAL DIVISION OF STRYKER CORPORATION, PORTAGE, MI - 483 (6/26/2012); STRYKER INSTRUMENTS, PORTAGE, MI - 483 (11/09/2012)
2012-8347	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Julie Myers Columbia University Medical Center	G.D. SEALE & COMPANY ORAL CONTRACEPTIVE - PACKAGE INSERT (1970)
2012-8348	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	COMPLAINT RECS

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		FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/		
2012-8349	11/21/2012 12/19/2012	FDA/OC/OES/DFOI/	Benjamin Lesser Benjamin Lesser	ENERGY DRINKS ADVERSE EVENTS - FOIA REQUESTS (11/01/2011 - 11/20/2012)
2012-8350	11/21/2012 12/19/2012	FDA/OF/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	COFFEE BEVERAGES AND CAFFEINE PRODUCTS - CAERS (11/1/2010 TO 10/31/2012)
2012-8351	11/21/2012 12/19/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	EFAVIRENZ, LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE- SBA
2012-8352	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Tyler Kenyon NORTHCOAST RESEARCH	NORLAND, FORT ATKINSON, WI - 483 (7/30/2012); COOPERSURGICAL, STAFFORD, TX - 483 (8/06/2012)
2012-8353	11/21/2012 12/19/2012	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Jane M. Hastedt G C HANFORD MFG CO	DOW CORNING HEALTHCARE INDUSTRIAL MATERIALS SITE, HEMLOCK, MI - EIR, 483 (05/01/2012 - 05/31/2012)
2012-8354	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Sleep Group Solutions	K011329, K921452
2012-8355	11/21/2012 12/19/2012	FDA/OMPT/CDRH/OCER/DFOI/	Dari Darabbeigi Persyst Development Corporation	K092625
2012-8356	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Versabond AB Bone Cement Laboratorios SL S.A.	K022688
2012-8357	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Kevin I. Goldberg Goldberg, Finnegan & Mester, LLC	MONSTER ENERGY DRINKS - FULL ADVERSE EVENT REPORTS (01/01/2004 - 10/23/2012)
2012-8358	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Versabond AB Bone Cement Laboratorios SL S.A.	K022688
2012-8359	11/23/2012 12/21/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amber Mynakha Northeast Regional Medical Center	DAPTOMYCIN - AERS (01/01/2003 - 11/01/2012)
2012-8360	11/23/2012 12/21/2012	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S ISSUED 08/29/2012 TO 11/21/2012

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2012-8361	11/23/2012 12/21/2012	ORA/ ORA/	William Figueroa Southwind Foods LLC DBA Great American S	594-0230269-5 - COLLECTION REPORT, ANALYST WORKSHEET
2012-8362	11/23/2012 12/21/2012	FDA/OMPT/CTP/OD/	Hagens Berman Sobol Shapiro LLP HAGENS BERMAN SOBOL SHAPIRO LLP	TOBACCO PRODUCT MANUFACTURERS, IMPORTERS, AGENTS - REPORTS SUBMITTED 2012
2012-8363	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrian Chew Pinsent Masons	FDA INACTIVE INGREDIENT GUIDE (1993)
2012-8364	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	Michael Pan Michael Pan	K122260
2012-8365	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	SHELDON T. BRADSHAW HUNTON & WILLIAMS LLP	AVID HEATLH INC; NORTHWEST NATURAL PRODUCTS INC; SUPPLEMENT SCIENCES INC, VANCOUVER, WA - EIR, 483, RECALL 11/20/10 TO PRESENT
2012-8366	11/23/2012 12/21/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Lesley Valle Boehringer Ingelheim	RODOLFO BORDONI, MARIETTA, GA - 483 (08/28/95)
2012-8367	11/23/2012 12/21/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	ZOSTAVAX - ACTION PACKAGE
2012-8368	11/23/2012 12/21/2012	FDA/OMPT/CDRH/OCER/DFOI/	David Dortch QIAGEN SCIENCES	PLEXUS, BAYAN LEPAS, MALAYSIA (01/01/2012 - 11/01/2012) - EIR
2012-8369	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cubist Pharmaceuticals Cubist Pharmaceuticals	DAPTOMYCIN - RPTS FOR CASES OF EOSINOPHILIC PNEUMONIA (01/01/2004 - 12/31/2010)
2012-8370	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Joseph Wilson joe wilson	MOUNTAIN DEW - CAERS (01/01/2000 - 11/21/2012)
2012-8371	11/23/2012 12/21/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	William McPhail Woodard & Curran	EVERGREEN ORCHARD FARM, HAMILTON, NJ - EIR ATTACHMENTS (03/22/12)
2012-8372	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Amber Mynakha Northeast Regional Medical Center	NOVOLOG, LANTUS - AERS (01/01/2000 - 11/01/2012)

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2012-8373	11/23/2012 12/21/2012	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N. BLUE, II ZETETIC	BAUSCH & LOMB - 34 BUNDLES CONTAINING OTC ENTRY NO 51620481492
2012-8374	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 203076 - SBA
2012-8375	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 021971 - SBA
2012-8376	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 022461 - SBA
2012-8377	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MATHERNE, MICHAEL MARK	CIPRO - AER
2012-8378	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORO/PA-FO/SEA-DO/SEA-CB/	Alec White HEALTHCOR MANAGEMENT LP	STARBUCKS - ADVERSE EVENTS, CONSUMER COMPLAINTS
2012-8379	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	TEAVANA - CONSUMER COMPLAINTS, ADVERSE EVENTS, STUDEIS RE POTENTIAL PESTICIDE CONTAMINATION
2012-8380	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 022459 - SBA
2012-8381	11/23/2012 12/21/2012	FDA/OGROP/ORO/CE-FO/CHI-DO/CHI-CB/	James Hurley HURLEY, JAMES	VEGETABLE JUICES, INC, BEDFORD PARK, IL - 483, COMPANY RESPONSE, EIR (03/01/2012 - 11/20/2012)
2012-8382	11/23/2012 12/21/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELE L. BUENAFE MORGAN LEWIS	SANTYL (COLLAGENASE) APRVL, LBLG, CO RESP

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2012-8383	11/23/2012 12/21/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	CooperVision, Inc. CooperVision, Inc.	COOPERVISION, PLEASANTON, CA - 483 (0 5/17/2012); COOPERVISION, W HENRIETTA, NY - 483 (05/29/12)
2012-8384	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Patrk Capital Management	STARBUCKS - AERS
2012-8385	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Sontakay, Suresh	FOOD CONTACT SUBSTANCE 15 4/00
2012-8386	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Sontakay, Suresh	FOOD CONTACT SUBSTANCE 685 3/20/07
2012-8387	11/23/2012 12/21/2012	FDA/OF/CFSAN/OCD/EOS/	Sontakay, Suresh	FOOD CONTACT SUBSTANCE 889 7/3/09
2012-8388	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 10/29/12-11/2/12
2012-8389	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/5-9/12
2012-8390	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/12-16/12
2012-8391	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/5-9/12
2012-8392	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8393	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 10/29/12-11/2/12
2012-8394	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/5-9/12
2012-8395	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 10/29/12-11/2/12
2012-8396	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/5-9/12
2012-8397	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 10/29/12-11/2/12

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2012-8398	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 11/5-9/12
2012-8399	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/12/-16/12
2012-8400	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/5-9/12
2012-8401	11/26/2012 12/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANOSHIMA MD HOSPITAL FOR SICK CHILDREN	COPAXONE - AERS
2012-8402	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAYTON, KATHRYN	DIETARY SUPPLEMENTS RECALLED DUE TO IMPROPER LBLG
2012-8403	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8404	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 10/27/12-11/2/12
2012-8405	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/5-9/12
2012-8406	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	CLOSED FOIA REQUESTS 11/12-16/12
2012-8407	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8408	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	CLOSED FOIA REQUESTS 11/5-9/12
2012-8409	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/5-9/12
2012-8410	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8411	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/12-16/12

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2012-8412	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 10/29/12-11/2/12
2012-8413	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/5-9/12
2012-8414	11/26/2012 12/24/2012	ORA/OCI/ ORA/OCI/	KAREN C KOSKI LAZARD CAPITAL MARKETS	ABIOMED - SUBPOENA 10/26/12 RECS
2012-8415	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	THEO EMISON EMISON HULLVERSON LLP	DR MICHAEL DRAKE, STANFORD UNIV - DIAGNOSIS AND/OR TREATMENT OF CHRONIC CEREBROSPINAL VENOUS INSUFFICIENCY (CCSVI) CORR, RPTS, INVESTIGATIONS, ETC
2012-8416	11/26/2012 12/24/2012	FDA/OMPT/CDRH/OCER/DFOI/	MEGAN STORRIE MELLINO ROBENALT LLC	INDIVIDUAL RECS - MAUDE RPT
2012-8417	11/26/2012 12/24/2012	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GABRIEL F ZAMBRANO FARMER JAFFE WEISSING EDWARDS FISTOS & LEHRMAN PL	BOEHRINGER INGELHEIM PHARMA GMBH & CO - PRADAXA CAPS (DEBIGATLAN ETETILATE) NDA 22-512 RECALL RECS
2012-8418	11/26/2012 12/24/2012	FDA/OF/CFSAN/OCD/EOS/	DAVID W PLUNKETT JD JM CENTER FOR SCIENCE IN PUBLIC INTEREST	VIBRIO VULNIFICUS RISK CALCULATOR - MEMOS, EMAILS, TRANS, ETC 2007 TO PRESENT
2012-8419	11/26/2012 12/24/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN BLOCH JOHNS HOPKINS MEDICINE DEPT OF NEUROLOGY	LORAZEPAM INTENSOL - ANDA RECS
2012-8420	11/26/2012 12/24/2012	FDA/OF/CFSAN/OCD/EOS/	CHRISTOPHER HENDEL CONSUMERS UNION OF THE U.S., INC	ENERGY DRNKS - CAERS 4/12/12 TO PRESENT
2012-8421	11/26/2012 02/01/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-	David Mangione FDAZILLA	PFIZER, PEARL RIVER, NY; HOSPIRA, ROCKY MOUNT, NC; CATALANT SOLUTIONS, BELGIUM - 483

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		DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OC/OES/DFOI/		
2012-8422	11/26/2012 12/24/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	GJ McGarity GJ McGarity	LYRICA - AERS
2012-8423	11/26/2012 12/24/2012	OM/OMP/DODM/	ronald piana Ronald Piana	ADVISORY COMMITTEE MEETING MINUTES - HYBRITECH INC. (06/29/93)
2012-8424	11/26/2012 12/24/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Marylalice Gill The Telegraph of Nashua, NH	SMARTPHONE APPS - COMPLAINTS FROM NEW ENGLAND RESIDENTS (11/08/2012 - 11/14/2012)
2012-8425	11/26/2012 12/24/2012	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	MARIA GRAZIA VIMERCATI APTALIS PHARMA SRL	APTALIS PHARMA SRL, ITALY - QUALITY ASSURANCE PROFILE (QAP)
2012-8426	11/26/2012 12/24/2012	CVM/OCD/ FDA/OC/OES/DFOI/	LYNNE TERRY OREGONIAN	JERKY PET TREATS FROM CHINA - INVESTIGATION RECS, LAB TESTS, NAMES OF MFRS, ETC 2007 TO PRESENT
2012-8427	11/26/2012 12/24/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MURIEL ASHIE MEDTRONIC INC	OSTEOTECH INC, SHREWSBURY, NJ - EIR 10/6/10-12/9/10
2012-8428	11/26/2012 12/24/2012	FDA/OC/OES/DFOI/	Brian Lester MANNING & NAPIER ADVISORS INC	NOVARTIS, SANDOZ - 483 (06/11 TO PRESENT)
2012-8429	11/27/2012 12/26/2012	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-	Michael McBride Michael McBride	INDIVIDUAL RECS

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		DO/NWE-CB/		
2012-8430	11/27/2012 12/26/2012	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Nicole M. Oliynyk ARIAD Pharmaceuticals Inc.	ASH STEVENS, RIVERVIEW, MI - EIR (01/01/2012 - 12/31/2012)
2012-8431	11/27/2012 12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	Meredith Reynolds EPIMED INTERNATIONAL INC	K090995
2012-8432	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Breggin, M.D. Peter R. Breggin, M.D.	ACZONE - AERS (01/01/2004 - 11/26/2012)
2012-8433	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Sarah Sorscher PUBLIC CITIZEN	COMPOUNDING PHARMACIES - 483S (04/01/2002 TO PRESENT)
2012-8434	11/27/2012	FDA/OGROP/ORA/SE-FO/ATL-	Ashlea Surles	BAXTER HEALTHCARE, MARION, NC - CORR, 483,

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	12/26/2012	DO/ATL-CB/	WLOS-TV	WARNING LETTER, ETC (01/01/2012 - 11/26/2012)
2012-8435	11/27/2012	ORA/	Andrew Kahn	ST JUDE MEDICAL, ARECIBO, PR - UNREDACTED 483
	12/26/2012	ORA/	UNITE HERE	(09/17/2012 - 11/25/2012)
2012-8436	11/27/2012	FDA/OMPT/CDER/ORP/DIDP/	joseph barton	CORTICOTROPIN/ACTH - ANNUAL FILINGS
	12/26/2012	FDA/OMPT/CDER/ORP/DIDP/	barton, joseph	
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
2012-8437	11/27/2012	FDA/OMPT/CDER/ORP/DIDP/	Mark Thomas	TENOFIR 1% GEL - PROTOCOL
	12/26/2012	FDA/OMPT/CDER/ORP/DIDP/	Noseweek Magazine	
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
2012-8438	11/27/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	RICHARD N SHAPIRO	HOWMEDICA OSTEONICS CORP - ABG II MODULAR HIP
	12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD N SHAPIRO LAW OFCS	REPLACEMENT K092406
2012-8439	11/27/2012	FDA/OC/OES/DFOI/		ENERGY DRINKS - WARNINGS
	12/26/2012		CROSBY T50417, COURTNEY	
2012-8440	11/27/2012	FDA/OMPT/CTP/OD/	AUSTIN G STEEVES IV	GENERAL SNUS, AUSTIN, TX - INVESTIGATION RECS
	12/26/2012		AUSTIN/TRAVIS COUNTY HEALTH AND HUMAN SERVICES	
2012-8441	11/27/2012	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WAYNE SADOWSKI	NOVARTIS PHARMACEUTICALS CORP, EAST HANOVER, NJ
	12/26/2012		NOVARTIS PHARMACEUTICALS CORP	- EIR, 483, CORR 8/13-23/12
2012-8442	11/27/2012	FDA/OMPT/CDER/ORP/DIDP/	DAVID C WEBER	MUTUAL PHARM - PREDNISONE ANNUAL RPT 1955 TO
	12/26/2012	FDA/OMPT/CDER/ORP/DIDP/	BEHREND & ERNSBERGER PC	PRESENT
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
2012-8443	11/27/2012	FDA/OMPT/CDER/ORP/DIDP/	DAVID C WEBER	UPJOHN PHARMS/PHARMACIA - DELTASONE ANNUAL
	12/26/2012	FDA/OMPT/CDER/ORP/DIDP/	BEHREND & ERNSBERGER PC	RPTS 1955 TO PRESENT
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
2012-8444	11/27/2012	FDA/OMPT/CDER/ORP/DIDP/	DAVID C WEBER	ROXANE LABS - PREDNISONE ANNUAL RPT 1955 TO
	12/26/2012	FDA/OMPT/CDER/ORP/DIDP/	BEHREND & ERNSBERGER PC	PRESENT
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		

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2012-8445	11/27/2012 12/26/2012	FDA/OGROP/ORPA-FO/LOS-DO/LOS-CB/	RANIL M FERNANDO BIOSCREEN TESTING SERVICES INC	MICRO QUALITY LABS INC, BURBANK, CA - EIRS, 483S, WARNING LTRS LAST 5 YRS
2012-8446	11/27/2012 12/26/2012	ORA/ ORA/	DAVID BLOCH MEDTRONIC	ST JUDE MEDICAL, SYLMAR, CA - 483, CO RESP 10/17/12
2012-8447	11/27/2012 01/07/2013	FDA/OO/OFBA/OAGS/	JEFF STACHEWICZ FOIA GROUP INC	HHSF223200850014I - TASK ORDER HHS0001, AWARD TYPE, 2011 SPENDING, ETC
2012-8448	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kenneth Woliner, MD Kenneth Woliner, MD	HCG - AERS (01/01/1973 - 12/01/2012)
2012-8449	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	KEITH STONEBACK AGILE SCIENCES	SEMPRUS (TELEFLEX) - APRVL OF NEW MATERIAL FOR CATHETERS
2012-8450	11/27/2012 12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	LISA ANDERSON CONMED CORP	BIRTCHE MEDICAL SYSTEMS INC - HYFRECATOR K800617
2012-8451	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	Lauren Farruggia Hyman, Phelps and McNamara	ROCKSTAR ENERGY DRINKS - CAERS (01/01/04-10/23/12)
2012-8452	11/27/2012 12/26/2012	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Janie Gwinn WATSON LABORATORIES INC	WATSON PHARMACEUTICALS/LABORATORIES - MTG MINUTES
2012-8453	11/27/2012 12/26/2012	FDA/OF/CFSAN/OCD/EOS/	LAUREN FARRUGGIA Hyman, Phelps & McNamara, P.C.	COFFEE BEVERAGES - CAERS 1/1/04 TO 10/23/12
2012-8454	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TONYA SAUSSER TARSA THERAPEUTICS INC	SANDOZ GMBH, KUNDL - 483 10/3-12/12
2012-8455	11/27/2012 12/26/2012	FDA/OF/CFSAN/OCD/EOS/	ELBEK, GAIL	SOY INFANT FORMULA & FOOD - CAERS
2012-8456	11/27/2012 12/26/2012	FDA/OMPT/CDRH/OCER/DFOI/	NEELMEGH, RAMESH	MEDICVISION - SAFECT PICTURE ARCHIVING AND COMMUNICATIONS SYS
2012-8457	11/27/2012	FDA/OMPT/CDER/GRP/DIDP/		ZOSTAVAX - VAERS

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	12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHAPIRO, ELAINE L	
2012-8458	11/27/2012 12/26/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	SILVER NITRATE - AERS
2012-8459	11/27/2012 12/26/2012	FDA/OF/CFSAN/OCD/EOS/	HELLEN A OKETCH PHD UNITED STATES PHARMACOPEIA	AGMATINE SULPHATE - CAERS 1/05 TO 5/12
2012-8460	11/27/2012 12/26/2012	FDA/OF/CFSAN/OCD/EOS/	HELLEN A OKETCH PHD UNITED STATES PHARMACOPEIA	N-ACETYL-D-GLUCOSAMINE - CAERS 1/05 TO 5/12
2012-8461	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2012-7908
2012-8462	11/27/2012 12/26/2012	FDA/OC/OES/DFOI/	BRIAN LESTER MANNING & NAPIER ADVISORS INC	SANDOZ, NOVARTIS - 483S, WARNING LTRS 6/11 TO PRESENT
2012-8463	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K073556
2012-8464	11/28/2012 12/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 090008 - TENTATIVE APPROVAL LETTER
2012-8465	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2012-7404
2012-8466	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2012-7914
2012-8467	11/28/2012 12/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMITIZA - AERS (11/02/2009 - 11/27/2012)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8468	11/28/2012 12/27/2012	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Helena Mateus-Martins J&K Fresh East a div of 721 Logistics	ENTRY 97E-0005593-0 - ANALYTICAL REPORT
2012-8469	11/28/2012 12/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahlaqa LUNDBECK INC	NDA 11665 (MESTINON ER TABLETS) - SBA
2012-8470	11/28/2012 12/27/2012	FDA/OF/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps and McNamara	ROCKSTAR ENERGY ADVERSE EVENTS - 83060, 86399, 87069, ETC
2012-8471	11/28/2012 12/27/2012	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Marie Sullivan and Suzanne Robinson Pain Consultants of West Florida, PA	SAMPLE RESULTS
2012-8472	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K090183
2012-8473	11/28/2012 12/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul J. Davis Paul J. Davis	PHENYTOIN - DETAILED REPORTS OF LEFT BUNDLE BRANCH BLOCK (01/01/2001 - 12/31/2011)
2012-8474	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll MEDOVATIONS INC	K061937
2012-8475	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	BIOMET MICROFIXATION - AER
2012-8476	11/28/2012 12/27/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GONZALES, GRACE	FORTICAL SPR - AER
2012-8477	11/28/2012 12/27/2012	FDA/OC/OES/DFOI/	JACKIE HERNDON ZAREMBA BROWNELL ET AL	CIPROFLOXACIN - RECS CERT
2012-8478	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-	Doe J	CMPLNT

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		DO/LOS-CB/		
2012-8479	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN STRANGE WELLS FARGO SECURITIES	HEARTWARE VENTRICULAR ASSIST SYS - SAFETY & EFFECTIVENESS PMA P100047
2012-8480	11/28/2012 12/27/2012	FDA/OMPT/CDRH/OCER/DFOI/	R. SCOTT JENNINGS TRANSPHOTON CORP	APEX DETECTOR ELECTRONICS & ACQUISITION INTERFACE MODEL XL4 K033001
2012-8481	11/28/2012 12/27/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	MERCK - HIB VACCINE RECALL
2012-8482	11/28/2012 12/27/2012	FDA/OO/ FDA/OO/OHR/	MARK L. FLATTEN WASHINGTON EXAMINER	EMPLOYEE DATA - OFFICIAL TIME USE
2012-8483	11/29/2012 12/28/2012	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (10/26/2012 - 11/28/2012)
2012-8484	11/29/2012 12/28/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	COCA COLA - AERS
2012-8485	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Lisa Anderson ConMed Corporation	K33497
2012-8486	11/29/2012 12/28/2012	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	E Neely St. Jude Medical	BOSTON SCIENTIFIC - RESPONSE TO WARNING LETTER DATED 01/25/06
2012-8487	11/29/2012 12/28/2012	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	E neely St. Jude Medical	MEDTRONIC CDRM - WARNING LETTER RECS (11/09/2009 - 11/01/2012)
2012-8488	11/29/2012 12/28/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	PEPSI - AERS
2012-8489	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	John P. Waters Whip Mix Corporation	K925375
2012-8490	11/29/2012 12/28/2012	FDA/OO/OFBA/OAGS/	Gina T Weismann TD Equipment Finance, Inc.	CONTRACTING OFFICER WARRANT OF AUTHORITY
2012-8491	11/29/2012 12/28/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rita Choi George Mason Law & Economic Center	APPROVABLE LETTERS, NOT APPROVABLE LETTERS, COMPLETE RESPONSE LETTERS FOR LISTED DRUGS (06/26/1997 - 11/28/2012)
2012-8492	11/29/2012 12/28/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	PEPSI ENERGY DRINKS - AERS

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2012-8493	11/29/2012 12/28/2012	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	E Neely St. Jude Medical	GUIDANT CORPORATION, ST PAUL, MN - RESPONSE TO 483 ISSUED 2/09/06
2012-8494	11/29/2012 12/28/2012	FDA/OF/CFSAN/OCD/EOS/	Shailini Rao Eton Park Capital Management, L.P.	PEPSI - AERS
2012-8495	11/29/2012 12/28/2012	FDA/OF/CFSAN/OCD/EOS/	Omari Ramirez Water Island Capital, LLC	TEAVANA HOLDINGS - SAMPLE ANALYSIS
2012-8496	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kevin A Henry UNIVERSITY OF UTAH	MAMMOGRAPHY FACILITIES - NUMBERS OF MACHINES, CAPACITY, DIFFUSION, ETC (01/01/2003 - 12/31/2011)
2012-8497	11/29/2012 12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE C BEARDSLEY ZUCKERMAN SPAEDER LLP	SUN PHARMACEUTICAL INDUSTRIES - SUMATRIPTAN AUTO-INJECTOR ANDA 09-0358 SBA, APRVL PKG
2012-8498	11/29/2012 12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE C BEARDSLEY ZUCKERMAN SPAEDER LLP	INTELLIJECT - AUVI-Q (EPINEPHRINE INJ USP) NDA 20-1739 SBA, APRVL PKG
2012-8499	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON, LEROY LESLIE	DESIGNATION FORM FDA 3429 - ALL VERSIONS THAT EXISTED PRIOR TO THE ASSIGNMENT OF THE FORM
2012-8500	11/29/2012 12/28/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN B BRAUNSTEIN VOUTE LOHRFINK MAGRO LLP ET AL	ASACOL (MESALAMINE) - AERS
2012-8501	11/29/2012 12/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JENNIFER GRAMLING SAMSTER KONKEL ET AL	WHEATON FRANCISCAN HEALTHCARE-FRANKLIN - TETANUS VACCINE RECS (CERTIFIED)
2012-8502	11/29/2012 12/28/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ ORA/ ORA/	PETER D LOFTUS Dow Jones & Company	OHM LABORATORIES, NEW BRUNSWICK, NJ - 483'S; RANBAXY LABS - ATORVASTIN CALCIUM ANDA 07-6477 CO RESP 11/30/11 TO PRESENT
2012-8503	11/29/2012 12/28/2012	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	NEIL SHEEHY NEIL SHEEHY	ETHICON (JOHNSON & JOHNSON CO) - FIBRIN PAD PROD LICENSE APPL RESP LTR, LBLG, CO RESP 10/5/12
2012-8504	11/29/2012 12/28/2012	FDA/OC/OES/	HENSON SR., J. DONALD	LAURIE LENKEL - NAME & POSITION OF THE INDIVIDUAL GIVING THE ASSIGNMENT, CORR
2012-8505	11/29/2012	FDA/OF/CFSAN/OCD/EOS/		VOLUNTARY NATIONAL RETAIL FOOD REGULATORY

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	12/28/2012	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	CORBETT, SUZANNE	PROGRAM STANDARDS, ASHFIELD, MA - RECIPIENTS OF FUNDING, COLLECTION FORM. LIST OF VENDORS, ETC
2012-8506	11/29/2012 12/28/2012	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Siobhan Briley Sullivan & Worcester LLP	AMERICAN DIAGNOSTICA, STAMFORD, CT - 510K SUBMISSIONS; 483, WARNING LETTERS, ETC
2012-8507	11/29/2012 12/28/2012	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Tony Taylor AESCULAP	PREMIER RESEARCH, PHILADELPHIA, PA - 483 (01/01/2008 - 11/28/2012)
2012-8508	11/29/2012 12/28/2012	FDA/OMPT/CDRH/OCER/DFOI/	Liu Jimin Hexalotus Technology Pte Ltd	K110186, K122136
2012-8509	11/30/2012 12/31/2012	CVM/OCD/ FDA/OF/CFSAN/OCD/EOS/	Carey Gillam/Reuters REUTERS	BNF 000124, DAS-68416-4, BNF 000125, MON 87708
2012-8510	11/30/2012 03/20/2013	FDA/OMPT/CTP/OD/ OC/COS/OES/ OC/COS/OES/	elliott favus FAVUS INSTITUTIONAL RESEARCH LLC	MENTHOL IN CIGARETTES - RECS (01/01/2011 - 12/31/2011)
2012-8511	11/30/2012 03/20/2013	FDA/OMPT/CTP/OD/ OC/COS/OES/ OC/COS/OES/	Elliot Favus FAVUS INSTITUTIONAL RESEARCH LLC	MENTHOL IN CIGARETTES - RECS (01/01/2012 - 11/29/2012)
2012-8512	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	pharmacokinetic data of Pitressin (vasopressin injection) UNIVERSITY OF HOUSTON COLLEGE OF OPTOMETRY	PITRESSIN - CLEARANCE DATA
2012-8513	11/30/2012 12/31/2012	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JoNel N. Aleccia MSNBC.COM	NEW ENGLAND COMPOUNDING CENTER - MEDWATCH RPTS (05/21/2012 - 11/29/2012)
2012-8514	11/30/2012 12/31/2012	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/ OM/OMP/DODM/	Joanne Matusko NastLaw, LLC	MIRENA - APPLICATIONS, MANUALS, CORR, ETC

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2012-8515	11/30/2012 12/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Friedman Morgan Stanley	XIAFLEX - STATISTICAL ANALYSIS PLAN FOR PHASE THREE
2012-8516	11/30/2012 12/31/2012	FDA/OF/CFSAN/OCD/EOS/	Josh James BRYAN CAVE LLP	OCEAN SPRAY CRAISINS, NISSIN TOP RAMEN, SABRA HUMMUS, ETC - CAERS
2012-8517	11/30/2012 12/31/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC INC	SEXY HAIR STYLING AND TREATMENT PRODS ENTRY #EHP00759408 - RECS
2012-8518	11/30/2012 12/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	ALISON M AGNEW PILLSBURY WINTHROP SHAW PITTMAN LLP	2012-6833
2012-8519	11/30/2012 12/31/2012	FDA/OF/CFSAN/OCD/EOS/	GUBEN, ALISON	COCA COLA/DIET COKE, PEPSI COLA/DIET PEPSI, JOLT COLA, ETC - CAERS
2012-8520	11/30/2012 02/01/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	DANIEL G JARCHO MCKENNA LONG & ALDRIDGE LLP	IEH LABORATORIES & CONSULTING GROUP - PATHOGEN PREVALENCE/BASELINE STUDY IN FRESH PRODUCE CONTRACTS, INVOICES, CORR, ETC
2012-8521	11/30/2012 12/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TENECIA SULLIVAN SALAMANDRA LLC	METHYLENE BLUE - ISRS 3236013-5, 3839924-2, 3989080-5, ETC
2012-8522	11/30/2012 12/31/2012	FDA/OF/CFSAN/OCD/EOS/	GUBEN, ALISON	COFFEE - CAERS
2012-8523	11/30/2012 12/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joyce Lee MORRISON & FOERSTER LLP	LSD - APPROVALS, WARNING, DISCLOSURE
2012-8524	11/30/2012 12/31/2012	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	PAR PHARMS - ANDA 91-340, ANDA 91-341 APRVL LTRS

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2012-8525	11/30/2012 12/31/2012	ORA/ ORA/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	R IAN KLUGE Hyman Phelps and McNamara PC	FRESH FISH FILETS ENTRY #235-1509680-0 - SHIPPING & PACKING RECS
2012-8526	11/30/2012 12/31/2012	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MCKENZIE CATO Hyman Phelps and McNamara PC	FLORIDA BIOLOGIX, ALACHUA, FL - RECS
2012-8527	11/30/2012 12/31/2012	FDA/OO/OFBA/OAGS/	FOI Services, Inc.	NATIONAL ENVIRONMENTAL HEALTH ASSN AWARD NUMBER U45FD 004325 - COOPERATIVE AGREEMENT 9/16/11, 8/14/12, 8/29/12, ETC
2012-8528	11/30/2012 12/31/2012	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	PROSURG - EVA K001576
2012-8529	11/30/2012 12/31/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	SPARHAWK LABORATORIES INC, LENEXA, KS - EIRS, 483S 6/1/05 TO PRESENT
2012-8530	11/30/2012 12/31/2012	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	KIM C CAPONE PORZIO BROMBERG & NEWMAN PC	PFIZER INC, NEW YORK, NY - EIR, 483 101/15/12
2012-8531	11/30/2012 12/31/2012	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DANIEL STEIN RICHARDS KIBBE & ORBE LLP	ABIOMED INC, DANVERS, MA - IMPELLA RECOVER LP 2.5 PERCUTANEOUS CARDIAC SUPPORT SYS CORR 1/1/08 TO PRESENT
2012-8532	12/03/2012 01/02/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MIJIB U. QIDWAI GRIFOLS BIOLOGICALS INC	BAXTER, LOS ANGELES, CA - EIR, 483 10/12
2012-8533	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	BELMONT INSTRUMENT CORP, BILLERICA, MA - BUDDY PLUS FLUID WARMER - K062774
2012-8534	12/03/2012 01/02/2013	FDA/OF/CFSAN/OCD/EOS/	ALVIN J LORMAN LAW OFC	FCN 1177
2012-8535	12/03/2012 01/02/2013	FDA/OF/CFSAN/OCD/EOS/	ALVIN J LORMAN LAW OFC	FCN 1188
2012-8536	12/03/2012 01/02/2013	FDA/OF/CFSAN/OCD/EOS/	ALVIN J LORMAN LAW OFC	FCN 1145
2012-8537	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	JIM KUSTERS MORIA INC	K090626

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2012-8538	12/03/2012 01/02/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	McKENZIE CATO Hyman, Phelps and McNamara	ORGAN RECOVERY SYSTEMS INC - RECS
2012-8539	12/03/2012 01/14/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	STEVEN D. BROCK JOHNSON LAW PLC	INDIVIDUAL RECS
2012-8540	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jing Ge Ge, Jing	HEARTWARE VENTRICULAR ASSIST DEVICE - STUDY DATA FOR 100 PATIENTS
2012-8541	12/03/2012 01/02/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Megan Mularczyk Pretzinger, Liz	INDIVIDUAL RECS
2012-8542	12/03/2012 01/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21951
2012-8543	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carey Folk New Country, LLC	K052732
2012-8544	12/03/2012 01/02/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Dominic DeMuro PFIZER, INC	PFIZER, SANFORD, NC - EIR (11/2011)
2012-8545	12/03/2012 01/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KAVITA SRIVASTAVA TARO PHARMACEUTICALS USA INC	GLENMARK GENERICS - FLUTICASONE PROPIONATE SBA, CHEMISTRY RVW, LBLG, ETC
2012-8546	12/03/2012 01/02/2013	FDA/OC/OES/DFOI/	Silvia Gambardella WTVD-TV/ ABC	PET JERKY TREATS - COMPLAINTS FROM NORTH CAROLINA
2012-8547	12/03/2012 01/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	HYCANTIN - APPROVAL, LABELING, MEDICAL REVIEW, ETC
2012-8548	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Emily Nugent Dickson Geesman LLP	K091057, K092356, K100403
2012-8549	12/03/2012 01/02/2013	FDA/OF/CFSAN/OCD/EOS/	Anna Edney BLOOMBERG NEWS	STARBUCKS COFFEE, HOSTESS TWINKIES - CAERS (01/01/2004 - 10/19/2012)
2012-8550	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K033474

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2012-8551	12/03/2012 01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Blinn Pura Vida Funds	P950022 S014
2012-8552	12/03/2012 01/02/2013	FDA/OC/OES/DFOI/	VIDA JOHNSON WONDER FIBER MASSAGE PRODUCT INC	HEALTH CARE THERAPEUTIC LIQUID - APRVL
2012-8553	12/03/2012 01/02/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K011144
2012-8554	12/03/2012 01/02/2013	FDA/OF/CFSAN/OCD/EOS/	GUBEN, ALISON	RED BULL - AER 1/04 TO 11/1/12
2012-8555	12/04/2012 01/03/2013	ORA/ ORA/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	BENJAMIN ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	HAINAN QINFU FOODS CO LTD - ENTRY #316-7043761-0 COLLECTION RPTS, STORAGE RECS, INVESTIGATIONS, ETC
2012-8556	12/04/2012 01/03/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	PAUL W TRIPP LINCARE INC	MEDILINK HOMECARE INC, NJ, PA - EIRS, 483S, WARNING LTRS 1/105 TO PRESENT
2012-8557	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI HOGAN LOVELLS LLP	FIRST VERSION, FINAL VERSION OF FORM FDA 356H
2012-8558	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI HOGAN LOVELLS US LLP	MARINOL NDA 18-651, DESYREL NDA 18-207, BUPRENEX NDA 18-401 - APRVL LTRS, FORM FDA 356H
2012-8559	12/04/2012 01/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANNE MUTASHI HOGAN LOVELLS LLP	CONTROLLED SUBSTANCES ACT - FDA DECISION TO INCLUDE ON THE FORM FDA 356H LANGUAGE THAT APPLIES TO PROPOSED DRUG SCHEDULING
2012-8560	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL B SNELLINGS PENTON LAW FIRM	INTUITIVE SURGICAL INC - DA VINCI SURGICAL SYS K081207 NOTICES, CMLPTS, MDRS, ETC
2012-8561	12/04/2012 01/03/2013	OM/OMP/DODM/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	DKT 1980N-0218
2012-8562	12/04/2012	OC/OCC/	ANDREW HACK MD PHD	GILEAD SCIENCES - MTG MINS, TRANS, AGENDA, ETC 11/8/12

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	01/03/2013		MILLENNIUM MANAGEMENT LLC	
2012-8563	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID C WEBER BEHREND ERNSBEERGER, PC	UPJOHN PHARMS, MUTUAL PHARM, ROXANE LABS - PREDNISONE AERS, LBLG CHANGES
2012-8564	12/04/2012 01/03/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	OWEN, EVAN D	MCNEIL CONSUMER HEALTHCARE, FORT WASHINGTON, PA - EIR, VIDEOS, IMAGES, ETC 4/19/12
2012-8565	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Yu-Ju Chiang Chung Yuang Christian University	K033474
2012-8566	12/04/2012 01/03/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Sandy Stagge CTI Clinical Trial and Consulting Servic	SANDARAM HARIHARAN, MEDICAL COLLEGE OF WISCONSIN - 483 AND RESPONSE (6/12/2000)
2012-8567	12/04/2012 01/03/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	UNIVERSITY OF CHICAGO BIOLOGICAL SCIENCES DIVISION IRB - 483 AND RESPONSE (7/8/2009)
2012-8568	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TRETINOIN - AERS
2012-8569	12/04/2012 01/03/2013	FDA/OF/CFSAN/OCD/EOS/	Marvin Friedman TR Services	CAS 7773-06-0
2012-8570	12/04/2012 01/03/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Edward W Skepnek VALNET INC	MEDIVATORS, CONROE, TX - EIR (04/03/2010 - 04/15/2010)
2012-8571	12/04/2012 01/03/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Christopher M. Brown Remington Medical, Inc.	REMINGTON MEDICAL, INC, ALPHARETTA, GA - EIR (10/19/10 - 12/17/10)
2012-8572	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22580
2012-8573	12/04/2012 01/03/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Edward W Skepnek VALNET INC	MEDIVATORS, CONROE, TX - EIR (02/15/2009 - 03/15/2009)
2012-8574	12/04/2012 01/03/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Cindy Ingold AMERICAN RED CROSS BLOOD SERVICES	AMERICAN RED CROSS MISSOURI/ILLINOIS, ST PETERS, MO - EIR 10/27/11

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2012-8575	12/04/2012 01/03/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Glenn Irish Glenn Irish Consulting	SHIRE, INC, LEXINGTON, MA - 483 (10/30/2011 - 11/30/2012)
2012-8576	12/04/2012 01/03/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Ben Eisler CBS This Morning	METOPROLOL SUCCENATE, FUROSEMIDE, LEVERTIRACETAM, ETC - AERS, BIOAVAILABILITY RECS, INSPECTION RECS, ETC
2012-8577	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	SHINGLES PREVENTION STUDY - INVESTIGATIONS, AUDITS
2012-8578	12/04/2012 01/03/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	KANT, KRISHNA	BOOST-ULTRA - ANALYSIS
2012-8579	12/04/2012	FDA/OGROP/ORA/SE-FO/ATL-	BRENDA M GARTZ	ROCHE CAROLINA INC, FLORENCE, SC - 483 1/27/10

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	01/03/2013	DO/ATL-CB/	ELI LILLY & CO	
2012-8580	12/04/2012 01/03/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	MICROBAC SOUTHERN TESTING RESEARCH DIVISION, WILSON, NC - EIR, 483 2/10
2012-8581	12/04/2012 01/03/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	BRENDA M GARTZ ELI LILLY & CO	DPT LABS, SAN ANTONIO, TX - EIR, 483 10/18/10-11/12/10
2012-8582	12/04/2012 01/03/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ROTATIONAL WARNING PLANS FOR SMOKELESS TOBACCO PRODUCTS SUBMITTED BY ALTRIA CLIENT SERVICES, PHILIP MORRIS USA, US SMOKELESS TOBACCO COMPANY LLC ETC
2012-8583	12/04/2012 01/03/2013	FDA/OF/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	ZERXIS PHARMS - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSION
2012-8584	12/04/2012 01/03/2013	FDA/OF/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	VIRTUS PHARMACEUTICALS LLC - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSIONS
2012-8585	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Slavens GE Healthcare	K052345
2012-8586	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Graves CRNA, ACNP, MSN Dayton Gastroenterology	PROPOVEN - AERS
2012-8587	12/04/2012 01/03/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS
2012-8588	12/04/2012 01/03/2013	FDA/OC/OES/DFOI/	Karen Troutman Dewey Publications Inc.	ORGANIZATIONAL INFORMATION
2012-8589	12/04/2012 01/03/2013	FDA/OF/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ BATTAGLIA ROSS DICUS & WEIN PA	BRECKENRIDGE PHARMACEUTICAL INC - METANX, CEREFOLIN, DEPLIN, ETC CORR, SUBMISSIONS
2012-8590	12/04/2012 01/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Kenney ENDO PHARMACEUTICALS	INDIVIDUAL SAFETY REPORTS
2012-8591	12/04/2012 01/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard O. Wood the Wood Burditt group	CDRH 513(G) C033022
2012-8592	12/04/2012	FDA/OF/CFSAN/OCD/EOS/	STEPHEN J WEIN ESQ	PAMLAB LLC - METANX, CEREFOLIN, DEPLIN, ETC CORR,

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	01/03/2013		BATTAGLIA ROSS DICUS & WEIN PA	SUBMISSIONS
2012-8593	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7694 REQUEST LETTER
2012-8594	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7715 REQUEST LETTER
2012-8595	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7506 REQUEST LETTER
2012-8596	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7769 REQUEST LETTER
2012-8597	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7782 REQUEST LETTER
2012-8598	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7784 REQUEST LETTER
2012-8599	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 11/1-30/2012
2012-8600	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 11/1-30/2012
2012-8601	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7734, 2012-7736, 2012-7737 REQUEST LETTER
2012-8602	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7641 REQUEST LETTER
2012-8603	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7509 REQUEST LETTER
2012-8604	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7693 REQUEST LETTER
2012-8605	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7133 REQUEST LETTER
2012-8606	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7328 REQUEST LETTER
2012-8607	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7239 REQUEST LETTER
2012-8608	12/05/2012	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2012-7403 REQUEST LETTER

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	01/04/2013		MERCK & CO., INC.	
2012-8609	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7497 REQUEST LETTER
2012-8610	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-4131
2012-8611	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7026
2012-8612	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7444 REQUEST LETTER
2012-8613	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7064 REQUEST LETTER
2012-8614	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6950
2012-8615	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7016
2012-8616	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7198 REQUEST LETTER
2012-8617	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6436
2012-8618	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6382
2012-8619	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6538
2012-8620	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7189 REQUEST LETTER
2012-8621	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7468 REQUEST LETTER
2012-8622	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7199 REQUEST LETTER
2012-8623	12/05/2012 01/04/2013	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	BRENDA M GARTZ ELI LILLY & CO	HOLLISTER-STIER (JUBLIANT), SPOKANE, WA - EIRS 2/12
2012-8624	12/05/2012 01/04/2013	FDA/OGROP/ORAP/CE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	PATHEON, CINCINNATI, OH - EIRS 12/11, 7/12

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2012-8625	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	HISUM PHARMACEUTICAL COMPANY LTD, ZHEJIANG, CHINA - EIRS 9/11, 7/12
2012-8626	12/05/2012 01/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	INIUITIVE SURGICAL INC, SUNNYVALE, CA -SURGICAL SYS & ENDOWRIST K050369, RESP LTR 4/29/05 (CERTIFIED)
2012-8627	12/05/2012 01/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	DA VINCI SURGICAL SYS- DAVINCI SURGICAL SYS ENDOSCOPIC INSTRUMENTS K043288, RESP LTR 3/3/05 (CERTIFIED)
2012-8628	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	WARNER CHILCOTT US - ESTRACE ANDA 08-069 SBA
2012-8629	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHANDRAN TIRUATTAR DR REDDY'S LABORATORIES INC	VALEANT INTL - ZOVIRAX NDA 18-604 SBA
2012-8630	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACKSON, EVA JO	ENALAPRIL MALEATE, METOPROLOL, NORTRIPTYLINE HCL, ETC - RECALL RECS, PI, AERS, ETC
2012-8631	12/05/2012 01/04/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ANDREA CLISURA FARUQI & FARUQI LLP	CMPLNT 29667
2012-8632	12/05/2012 01/04/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	CAMPBELL - CREAM OF SHRIMP SOUP CMPLNT
2012-8633	12/05/2012 01/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARIAH MONTGOMERY CHANGE TO WIN	ALMUS PHARMACEUTICALS SINGAPORE PTE LTD; IMPORTS REFUSALS, EIRS,ETC 2005 TO PRESENT
2012-8634	12/05/2012 01/04/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	CAFFEINE INTAKE BY THE US POPULATION 9/09

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2012-8635	12/05/2012 01/04/2013	FDA/OF/CFSAN/OCD/EOS/	VERONICA S KNAPP HOGAN LOVELLS US LLP	SE RICHARD J DURBIN, CAFFEINE INTAKE BY US POPULATION 9/09
2012-8636	12/05/2012 01/04/2013	FDA/OF/CFSAN/OCD/EOS/	Desmonne Bennett BRYAN CAVE LLP	O.N.E. COCONUT WATER, ONE WORLD ENTERPRISES, ONE NATURAL EXPERIENCE - CAERS (03/01/2008 - 12/04/2012)
2012-8637	12/05/2012 01/04/2013	ORA/ ORA/	Nathan Ballard Sunrise Produce Inc.	SAMPLE RESULTS
2012-8638	12/05/2012 01/04/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Edward W Skepnek VALNET INC	FLEX MEDICAL, ASHEVILLE, NC - EIR 03/31/2011
2012-8639	12/05/2012 01/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7056 REQUEST LETTER
2012-8640	12/05/2012 01/04/2013	FDA/OF/CFSAN/OCD/EOS/	Edward McPike Stifel Nicolaus & Co	ENERGY DRINKS - FULL CAERS REPORTS LISTED
2012-8641	12/05/2012 01/04/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 546
2012-8642	12/05/2012 01/04/2013	FDA/OF/CFSAN/OCD/EOS/	Charles Sohn Sohn, Charles	FAP 3B3713
2012-8643	12/05/2012 01/04/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	David Mangione FDAZILLA	HOSPIRA, MCPHERSON, KS - 483 (10/24/2012)
2012-8644	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 11/19-13/12
2012-8645	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 11/26-30/12
2012-8646	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/19-23/12
2012-8647	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 11/26-30/12
2012-8648	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/19-23/12
2012-8649	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 11/26-30/12
2012-8650	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/9-23/12

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2012-8651	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 11/26-30/12
2012-8652	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/19-23/12
2012-8653	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 11/26-30/12
2012-8654	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	PATHEON, FERENTINO, ITALY - 483S 5/11, 11/11
2012-8655	12/06/2012 01/07/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	BRENDA M GARTZ ELI LILLY & CO	PHILIPS PLASTICS CORP, MENOMONIE, WI - EIRS 11/11
2012-8656	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGELHEIM, VIENNA, AUSTRIA - EIRS 3/12
2012-8657	12/06/2012 01/07/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	FARRELL MENDELSON, CARDIOLOGY PC, BIRMINGHAM, AL - 483S 6/04 TO 11/12
2012-8658	12/06/2012 01/07/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	RICHARD KRAUSE, PARKRIDGE PROF PLZ SOUTH, CHATTANOOGA, TN - 483S 8/06 TO 11/12
2012-8659	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANJAY H SHARMA HETERO USA INC	MEPRON (ATOVAQUONE) ORAL SUSPENSION (MEPRON) - CHEMISTRY RVW, BIOQV RVW, ADMINISTRATIVE RECS
2012-8660	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	M MELISSA BALTZ BUTLER SNOW ET AL	AMS APOGEE VAULT SUSPENSION SYS K040537 (CERTIFIED)
2012-8661	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTIE EVANS HILL ROM	STRYKER - IBED WIRELESS WITH IBED AWARENESS K103536
2012-8662	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	WASHINGTON, MARK A	POLICIES & PROCEDURES FOR THE GENERAL DISCHARGE OF ALL DEBT

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2012-8663	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	GABRIEL F ZAMBRANO FARMER JAFFE WEISSING EDWARDS FISTOS & LEHRMAN PL	BOEHRINGER INGELHEIM PHARMS - PRADAXA CAPS (DABIGATRAN ETEXILATE MESYLATE) RECALL RECS, CORR, NOTICES, ETC
2012-8664	12/06/2012 01/07/2013	FDA/OF/CFSAN/OCD/EOS/	MICHELE MITAL OLSSON FRANK WEEDA TERMAN MATZ PC	CAFFEINE INTAKE BY THE US POPULATION - RPT 9/09
2012-8665	12/06/2012 01/07/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	PATTI WALLER MARLER CLARK ATTYS	CHAMBERLAIN FARMS PRODUCE INC - SALMONELLA TYPHIMURIUM AND SALMONELLA NEWPORT MULTISTATE OUTBREAK CORR, LAB RESULTS, TRACE BACK, ETC
2012-8666	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PARAKKAL DEEPAK MD CENTER FOR THE STUDY OF COMPLEX DISEASES	ISRS 3910189, 3931338, 3931346, ETC 1/03 to 6/12
2012-8667	12/06/2012 01/07/2013	FDA/OF/CFSAN/OCD/EOS/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	DKT 2012F-0480 - FAP
2012-8668	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	HEARTWARE VENTRICULAR ASSIST SYS - MDRS
2012-8669	12/06/2012 01/07/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC AND FOREIGN DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - INSPS 10/1-31/12
2012-8670	12/06/2012 01/07/2013	ORA/ ORA/	Doe J	PURINA DOG FOOD - ALUMINUM POISONING CMLNT
2012-8671	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TERAZOSIN, HYTRIN - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2012-8672	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/	BRODY MULLINS WALL STREET JOURNAL	SAC CAPITAL, CR INTRINSIC - RECS, CORR 1/1/05 TO 12/1/12
2012-8673	12/06/2012 01/07/2013	OC/OM/OMP/DDM/	COLLEEN CAMPBELL SIDLEY AUSTIN LLP	DKT 1998P-0610
2012-8674	12/06/2012 01/07/2013	ORA/ ORA/	Doe J	RANBAXY - MEDICATION CONTAMINATION CMPLNT
2012-8675	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUDY F GORDON DVM CLINREG CONSULTING SERVICES INC	TRUEVISION SYSTEMS INC - K101861
2012-8676	12/06/2012 01/07/2013	OC/OM/OMP/DDM/	THOMAS FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT 1985N-0548, 1976G-0073
2012-8677	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K823115
2012-8678	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K852310
2012-8679	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Virginia Anello DOUGLAS & LONDON	K070177
2012-8680	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NYCOMED GMBH, BADEN-WUERTTEMBERG, GERMANY - EIR (04/19/12)
2012-8681	12/06/2012 01/07/2013	OC/OER/OPA/	XIN GE INDIVIDUAL	DR SHIMIN FANG - RECS RE INVITATION TO SPEAK AT FDA ON 11/10/12 SPEECH
2012-8682	12/06/2012	OM/OMP/DODM/	Mehul Govani	1995-S-0039

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	01/07/2013		PL DEVELOPMENTS	
2012-8683	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Edney BLOOMBERG NEWS	SIDNEY GILMAN - FINANCIAL DISCLOSURE FORMS (01/01/2002 - 12/05/2012)
2012-8684	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	KYOCERA Medical Corporation KYOCERA Medical Corporation	K011533
2012-8685	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K922005
2012-8686	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	Jennie Laton HASSARD BONNINGTON LLP	SKIN BLEACHING OTC DRUGS - PROPOSED RULE, TENTATIVE FINAL MONOGRAPH, NOTICE OF PROPOSED RULEMAKING, ETC
2012-8687	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	MARY SCHWAGER WHDH-TV INC	AIRLINE CATERERS - INSP LAST 3 YRS
2012-8688	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K030497
2012-8689	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K810925
2012-8690	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	2011-9188
2012-8691	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	2011-4550
2012-8692	12/06/2012 01/07/2013	ORA/ ORA/	Brittany Freeman WSMV TV	AMERIDOSE - COMPLAINTS REFERENCED IN 483
2012-8693	12/06/2012 01/07/2013	FDA/OC/OES/DFOI/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	2011-8937
2012-8694	12/06/2012 01/07/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 151606, 151607, 151881, ETC
2012-8695	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Willard Bond Wells III PRIVATE CITIZEN	AMARIN VASCEPA - RESPONSE LETTER CIRCULATED BY CDER EXCLUSIVITY BOARD

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2012-8696	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K031219
2012-8697	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K010322
2012-8698	12/06/2012 01/07/2013	ORA/ ORA/	Brittany Freeman WSMV TV	NECC, AMERIDOSE - PHOTOS, VIDEOS TAKING DURING INSPECTIONS
2012-8699	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Cody Medi USA, LP	K941926
2012-8700	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Virginia Anello DOUGLAS & LONDON	K823115
2012-8701	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brittany Freeman WSMV TV	ZZZQUIL - AERS (01/01/2010 - 12/05/2012)
2012-8702	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	DR KIMMO INGRAM, ORION PHARMA R&D, ESPOO, FINLAND - ALPRAZOLAM TABS ANDA 200-818 EIR 10/18-22/10
2012-8703	12/06/2012 01/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	FERNANDO SABA Laboratorios SL S.A.	K103816
2012-8704	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Tornetta Endo Pharmaceuticals Inc.	NDA 18401 - SBA
2012-8705	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	ZOSTAVAX - CORR, MEMOS, EMAIL ETC RE RISK ASSESSMENT
2012-8706	12/06/2012	FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN	DR F H VAN HEUVELN, XENDO DRUG DEVELOPMENT BV, BIOTECH CENTER, GRONINGEN, NETHERLANDS -

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	01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ORION PHARMA	ALPRAZOLAM TABS ANDA 200-818 EIR 10/4-8/10
2012-8707	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Burton WALL STREET JOURNAL	COMPOUNDING PHARMACIES - AERS
2012-8708	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	STEPHAN M JAKOB MD, INSELPITAL, BERN, SWITZERLAND - RECEDEX (DEXMEDETOMIDINE HCL INJ) NDA 21-038 EIR 3/26-29/12
2012-8709	12/06/2012 01/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANNE SOLKINEN ORION PHARMA	ANTHONY DUGARD MD, HOSPITAL DUPUYTREN, LIMOGES, FRANCE - RECEDEX (DEXMEDETOMIDINE HC; INJ) NDA 21-038 EIR 3/19-23/12
2012-8710	12/07/2012 01/08/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	KUTOL PRODUCTS CO, SHARONVILLE, OH; ACCUPAK MIDWEST INC, CINCINNATI, OH; MEDICAL QUANT USA INC, SOLON, OH - 483S 10/1-31/12
2012-8711	12/07/2012 01/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDA NEWS	GRESKO PRODUCTS INC, STAFFORD, TX; ADVANCED AESTHETIC CONCEPTS LP (PROFITSOLUTIONS MD), FT WORTH, TX - 483S 10/1-31/12
2012-8712	12/07/2012 01/08/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	CODY LABORATORIES INC, CODY, WY; CERAPEDICS INC, WESTMINSTER, CO - 483S 10/1-31/12
2012-8713	12/07/2012 01/08/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	DANMAR PRODUCTS INC, ANN ARBOR, MI; KREMERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN; ENZYME SOLUTIONS INC, GARRETT, IN - 483S 10/1-31/12
2012-8714	12/07/2012 01/08/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	THEOCHEM LABORATORIES INC, TAMPA, FL; SRI SURGICAL, TAMPA, FL; ASO LLC, SARASOTA, FL, ETC - 483S 10-1-31/12
2012-8715	12/07/2012 01/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	EXCELLA GMBH, FEUCHT, GERMANY; SANDOZ GMBH, KUNDL, AUSTRIA; UMAN PHARMA INC, CANDIAC, CANADA, ETC - 483S 10/1-31/12
2012-8716	12/07/2012 01/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	MALEM MEDICAL, NOTTINGHAM, UK; OY AJAT LTD, ESPOO, FINLAND; CREASPIRE SAS, PESSAC, FRANCE, ETC - 483S 10/1-31/12

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2012-8717	12/07/2012 01/08/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	HOSPIRA INC, MCPHERSON, KS - 483S 10/1-31/12
2012-8718	12/07/2012 01/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	NEOMPS INC, SAN DIEGO, CA; DAKO NORTH AMERICA INC, CARPINTERIA, CA; INNOVATIVE MED INC, IRVINE, CA, ETC - 483S 10/1-31/12
2012-8719	12/07/2012 01/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	CONKLIN COMPANY INC, SHAKOPEE, MN; ZYGA TECHNOLOGY INC, MINNEAPOLIS, MN; DANE TECHNOLOGIES, BROOKLYN PARK, MN, ETC - 483S 10-1-31/12
2012-8720	12/07/2012 01/08/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	ORTHO CLINICAL DIAGNOSTICS INC, RARITAN, NJ; PACON MFG CORP, SOMERSET, NJ - 483S 10/1-31/12
2012-8721	12/07/2012 01/08/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	RADIUS MEDICAL LLC, HUDSON, MA; IKONISYS INC, NEW HAVEN, CT; KEYSTONE DENTAL INC, BURLINGTON, MA, ETC - 483S 10/1-31/12
2012-8722	12/07/2012 01/08/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDA NEWS	HOWARD INSTRUMENTS INC, TUSCALOOSA, AL - 483S 10/1-31/12
2012-8723	12/07/2012 01/08/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	CHEMBIO DIAGNOSTIC SYSTEM INC, MEDFORD, NY; PROPPER MFG CO INC, LONG ISLAND CITY, NY; BUSSE HOSPITAL DISPOSABLES, HAUPPAUGE, NY, ETC - 483S 10/1-31/12
2012-8724	12/07/2012 01/08/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	BEST MEDICAL INTERNATIONAL INC (BEST NOMOS), PITTSBURGH, PA - 483S 10/1-31/12
2012-8725	12/07/2012 01/08/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	AESTHETIC AND RECONSTRUCTIVE TECHNOLOGIES INC, RENO, NV; TERARECON INC, FOSTER CITY, CA; SCITON INC, PALO ALTO, CA - 483S 10/1-31/12
2012-8726	12/07/2012 01/08/2013	FDA/OF/CFSAN/OCD/EOS/	SEAN HIGGINS, Esq ANDREWS THORNTON	MONSTER REHAB GREEN TEA & ENERGY; DIETARY SUPPLEMENTS CONTAINING EPIGALLOCATECHIN 3 GALLATE - AER
2012-8727	12/07/2012 01/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK E. LUPINETTI FIRST DATABANK	BULK INGREDIENTS FOR HUMAN RX COMPOUNDING - LBLG
2012-8728	12/07/2012 01/08/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	CUSTOM OCULAR PROSTHETICS INC, SEATTLE, WA; ELIXIR RESEARCH LLC, VASHON, WA; DE HOKANSON INC, BELLEVUE, WA - 483 10/12
2012-8729	12/07/2012 01/08/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	ABC COMPOUNDING CO INC, MORROW, GA; CAROLINA MEDICAL PRODUCTS CO, FARMVILLE, NC; CRYOLIFE INC, KENNESAW, GA - 483 10/12
2012-8730	12/07/2012	FDA/OGROP/ORA/CE-FO/BLT-	JOHNATHAN RICKMAN	AG ESSENCE INC, RICHMOND, VA; PHARMACEUTICALS

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	01/08/2013	DO/BLT-CB/	FDANEWS	INT'L INC, HUNT VALLEY, MD - 483 10/12
2012-8731	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	AKORN INC, DECATUR, IL; RAANI CORP, BEDFORD PARK, IL; HOME ACCESS HEALTH CORP, HOFFMAN ESTATES, IL - 483 10/12
2012-8732	12/07/2012 01/08/2013	FDA/OMPT/CTP/OD/	DESMOND JENSON Tobacco Control Legal Consortium	SMOKEMATE - ECIGARETTES INVESTIGATION
2012-8733	12/07/2012 01/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIO T.D. BARRERA BARRERA & ASSOCIATES	KRAMER LABS INC - CORR, WARNING LTR, CASE FLA 06-05
2012-8734	12/07/2012 01/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAVI DESHPANDE ACINO PRODUCTS LLC	TARO PHARMACEUTICALS - TERCONAZOLE VAGINAL SUPPOSITORY ANDA 077553, PROMETHAZINE HYDROCHLORIDE SUPPOSITORY ANDA 040603, PROMETHAZINE HYDROCHLORIDE SUPPOSITORY ANDA 040603 - SBA
2012-8735	12/07/2012 01/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAY WINCKLER WINCKLER & HARVEY LLP	LANX SPINAL FIXATION SYS K093285
2012-8736	12/07/2012 01/08/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/	ERIKA DUTHELY ENVIRONMENTAL WORKING GROUP	BRAZILIAN BLOWOUT - CMPLNTS, AER SINCE 1/11
2012-8737	12/07/2012 01/08/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	RELAXATION - AER, 1/04 TO PRESENT
2012-8738	12/07/2012 01/08/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	VICTORIA SCOTT HEMISPHERX BIOPHARMA	HEMISPHERX BIOPHARMA INC - INSP 11/27-28/12
2012-8739	12/07/2012 01/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL LOUIK ROSEN LOUIK ET AL	DEPUY ORTHOPAEDICS INC - 3 PEG MOD ROT PATELLA CEMENTED
2012-8740	12/07/2012 01/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WILSON, KATE	IVANO FRANKOVSK REGIONAL FORENSIC MEDICAL BUREAU, UKRAINE FEI 3007016079
2012-8741	12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	UNITED STATES SURGICAL CORP - LETTER FROM FDA RE

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	01/09/2013		FOI Services, Inc.	RECLASSIFICATION OF NONABSORBABLE PET SUTURES (07/05/1990)
2012-8742	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	ADVANCED BIORESEARCH ASSOCIATES - PETITION FOR RECLASSIFICATION RE SURGICAL SUTURES
2012-8743	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KYOCERA Medical Corporation KYOCERA Medical Corporation	K050327
2012-8744	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies Inc	K023941
2012-8745	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	JILL GOLDSTEIN GOLDSTEIN, JILL S	K122350
2012-8746	12/10/2012 01/09/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Charlotte Dannenfelser BD DIAGNOSTIC SYSTEMS	BD DIAGNOSTIC SYSTEMS, SPARKS, MD - EIR (04/23/10)
2012-8747	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2012-8748	12/10/2012 01/09/2013	FDA/OF/CFSAN/OCDEOS/	Rachel Johnson FOI Services, Inc.	FCN 647
2012-8749	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	Maryann Ivie COSGRAVE VERGEER KESTER LLP	FOIA REQUESTS RE INVACARE (02/01/2008 - 11/30/2012)
2012-8750	12/10/2012 01/09/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Eric Gandhi Robeco Investment Mgmt.	INVACARE CORP, OHIO - 483 (06/01/2011 - 08/31/2011)
2012-8751	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Willimas Shire Pharmacueticals	VYVANSE - AERS
2012-8752	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K092138
2012-8753	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K060119
2012-8754	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K011354
2012-8755	12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	Joakim Arwidson	K093982

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	01/09/2013		Hermes Medical Solutions	
2012-8756	12/10/2012 01/09/2013	OM/OMP/DODM/ FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	GENERAL AND PLASTIC SURGERY DEVICES PANEL MEETING - SUPPORTING MATERIALS (10/20/1988)
2012-8757	12/10/2012 01/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	AnnMarie Beattie Harmonized Customs Brokers, Inc	ENTRY G76-0129576-7 - LAB RESULTS
2012-8758	12/10/2012 01/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	MIGUEL WENCASLAO TREGNAGHI, ARGENTINA - EIR, 483, WARNING LETTER, ETC
2012-8759	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOGS 11/12-16/12
2012-8760	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/19-23/12
2012-8761	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/12-16/22
2012-8762	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 11/19-23/12
2012-8763	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/12-16/12
2012-8764	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DALILY LOG 11/19/23/12
2012-8765	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services, Inc.	FOI DAILY LOG 11/12-16/12
2012-8766	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	GLADYS B TONKINS Center for Regulatory Services, Inc.	FOI DAILY LOG 11/19-12/12
2012-8767	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/19/23/12
2012-8768	12/10/2012 01/09/2013	FDA/OC/OES/DFOI/	DEBI L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/12-16/12
2012-8769	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN A KNOLL COHEN & MALAD LLP	FRESSENIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE & NATURALYTE

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				GRANUFLO (POWDER) ACID CONCENTRATE K30497, K023985, K911459, ETC (CERTIFIED)
2012-8770	12/10/2012 01/09/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JONATHAN A KNOLL COHEN & MALAD LLP	FRESSENIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE & NATURALYTE GRANUFLO (POWDER) ACID CONCENTRATE MEMOS, CORR RECALL, ETC
2012-8771	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	XIGRIS (DROTRECOGIN ALFA); MERIDA (SIBUTRAMINE); REDUCITIL (SIBUTRAMINE), ETC - CLNCL INSP SUMMARIES
2012-8772	12/10/2012 01/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK - ZOSTAVAX VACCINE OSI CLNCL INSP SUMMARIES
2012-8773	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODES AS MEDICATION ERRORS 11/1-30/12
2012-8774	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CANDICE DURENCE OPTIMER PHARMACEUTICALS INC	DIFICID (FIDAXOMICIN) NDA 201-699 - ISR 8652998, 8691126
2012-8775	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RINGELHEIM, A	PROLIA - AERS
2012-8776	12/10/2012 01/09/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	LORI KERSEY CHARLESTON GAZETTE	YEAGER AIRPORT, CHARLESTON, WV; TRI-STATE AIRPORT, HUNTINGTON, WV; NORTH CENTAL WEST VIRGINA AIRPORT, CLARKSBURG, WV, ETC - EIRS 2011, 2012
2012-8777	12/10/2012 01/09/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SAN-	JANPAUL PORTAL FERRARO LAW FIRM	INDIVIDUAL RECS

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		DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/		
2012-8778	12/10/2012 01/09/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	ARL LBIOPHARMA INC (ANALYTICAL RESEARCH LABS), OKAHOMA CITY, OK - 483S
2012-8779	12/10/2012 01/09/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	STACI M TROLIAN BIOMET	DR MARK ALAN MIGHELL- CO RESP TO WARNING LTR 7/6/05
2012-8780	12/10/2012 01/09/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN A KNOLL COHEN & MALAD LLP	FRESSNIUS MEDICAL CARE NORTH AMERICA - NATURALYTE LIQUID ACID CONCENTRATE & NATURALYTE GRANUFLO (POWDER) ACID CONCENTRATE - EIRS, 483S 2006 (CERTIFIED)
2012-8781	12/10/2012 01/09/2013	FDA/OMPT/CTP/OD/	DESMOND JENSON Tobacco Control Legal Consortium	METRO SUPER SAVER - SMOKELESS TOBACCO PROD, MARBORO LIGHTS INVESTIGATION & FOLLOW-UP ACTION
2012-8782	12/10/2012 01/09/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Kristan Phillips MacroGenics	MEDIVATION, SAN FRANCISCO, CA - 483 (06/27/12)
2012-8783	12/10/2012 01/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	OBSERVATIONAL POST-LICENSURE SAFETY STUDY FOR ZOSTOVAX IN A US HEALTH MAINTENANCE ORGANIZATION
2012-8784	12/10/2012 01/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	POSTMARKET COMMITMENT 234570 - ANNUAL REPORT (6/18/2012), FINAL REPORT (12/30/2009)
2012-8785	12/10/2012	FDA/OMPT/CDRH/OCER/DFOI/	Elisabeth Neely	P920015 S017

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	01/09/2013		St. Jude Medical	
2012-8786	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	ATORVASTATIN - AERS
2012-8787	12/10/2012 01/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	E Neely St. Jude Medical	P920015 S090
2012-8788	12/10/2012 01/09/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Rebecca Maciel FoodScience Corporation	ABH NATURE'S PRODUCTS, FARMINGDALE, NY - 483 (06/01/2012 - 06/30/2012)
2012-8789	12/10/2012 01/09/2013	FDA/OF/CFSAN/OCD/EOS/ OM/OMP/DODM/	Merle Zimmermann (ext 106) AMERICAN HERBAL PRODUCTS ASSOCIATION	NEW DIETARY INGREDIENTS - ALL RECS
2012-8790	12/10/2012 01/09/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	ATORVASTATIN - CORR BETWEEN FDA AND RANBAXY, OHM RE NOVEMBER 2012 RECALL
2012-8791	12/10/2012 01/09/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Shannon Pettypiece BLOOMBERG NEWS	ENDO HEALTH SOLUTIONS, QUALITEST - CORR WITH FDA RE DECEMBER 2012 RECALL OF HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS
2012-8792	12/10/2012 01/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece BLOOMBERG NEWS	RANBAXY LABORATORIES, OHM LABORATORIES, TOANSA AND PUNJAB, INDIA - INSPECTION RECS (12/07/1995 - 12/07/2012)
2012-8793	12/10/2012 01/09/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Doe J	GC CORPORATION (GE AMERICA) - COMPLAINT FOLLOW UP
2012-8794	12/11/2012 01/10/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	BRENDA M. GARTZ ELI LILLY & CO	OSO BIOPHARMACEUTICALS, ALBUQUERQUE, NM - EIR 4/12

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2012-8795	12/11/2012 01/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	LONZA, BRAIN, BELGIUM - EIR 6/12
2012-8796	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	BRENDA M. GARTZ ELI LILLY & CO	EVONIK DEGUSSA CORP, LAFAYETTE, INDIANA - EIR 3/12
2012-8797	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Dennis R. Gwaltney DePuy Orthopaedics, Inc.	DEPUY ORTHOPAEDICS, WARSAW, IN - EIR (05/10/2011 - 06/07/2011)
2012-8798	12/11/2012 01/10/2013	FDA/OF/CFSAN/OCD/EOS/	Justin J. Prochnow Justin J. Prochnow	VARIOUS PRODUCTS - CAERS (07/01/2004 - 10/23/2012)
2012-8799	12/11/2012 01/10/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	GLAND PHARMA LTD, HYDERABAD, INDIA - EIR 8/12
2012-8800	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	BRENDA M. GARTZ ELI LILLY & CO	GIRINDUS AMERICA INC, CINCINNATI, OH - EIR 2/12
2012-8801	12/11/2012 01/10/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Dr. Michael Seminerio UNIVERSITY OF CHICAGO	TARCEVA - STUDY RESULTS
2012-8802	12/11/2012 01/10/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jeanna M Marraffa Pharm.D., DABAT Upstate NY Poison Center	LOPERAMIDE - AERS
2012-8803	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	BRENDA M. GARTZ ELI LILLY & CO	FISHER CLNCL SERVICES, ALLENTOWN, PA - EIR 11/11
2012-8804	12/11/2012 01/10/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OC/OES/DFOI/	Andrea Sudano Roccaro Andrea Sudano	ANTIBIOTICS - WEIGHT LOSS AND AERS

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2012-8805	12/11/2012 01/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Salvador Fornell Prez Dr. Fornell. Hospital Virgen del Rocío	EBI OSTEOGEN 20 - APPROVAL RECS
2012-8806	12/11/2012 01/10/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Samuel Medrano Private Individual	FRESENIUS MEDICAL CARE, BATTLE CREEK, MI - USE OF GRANUFLO AND NATURALYTE, SAFETY ISSUES
2012-8807	12/11/2012 01/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Chapman Stem Cell Partners LLC	BK110040
2012-8808	12/11/2012 01/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	KEITH CHASIN LAW OFFICE OF KEITH CHASIN	INDIVIDUAL RECS
2012-8809	12/11/2012 01/10/2013	FDA/OF/CFSAN/OCD/EOS/	Murray Carpenter Murray Carpenter	SUNKIST SODA - CAERS (09/01/2010 - 08/31/2011)
2012-8810	12/11/2012 01/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	ORI GOREN MOVING LIFE LTD	TZORA ACTIVE SYS LTD - ELITE ULTRA LIGHT COMPACT PORTABLE SCOOTER K052204; FREEFIDER LUGGIE SCOOTERS INC - MODEL 168-41T K110165; ELITE EXTRA LIGHT K052204
2012-8811	12/11/2012 01/10/2013	FDA/OF/CFSAN/OCD/EOS/	J. ANDREW MEYER, Esq. MORGAN & MORGAN	MARTEK BIOSCIENCES CORP - HORIZON ORGANIC MILK PLUS DHA OMEGA 3 DKT 2324
2012-8812	12/11/2012 01/10/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	CHRISTOPHER M. SHKRELI GOLDBERG SEGALLA	FOREVER CHEESE, LONG ISLAND, NY - FRESCOLINA RICOTTA SALATA LISTERIA OUTBREAK
2012-8813	12/11/2012 01/10/2013	CVM/OCD/	STEVE D. MATTERI CONTEMPORARY PRODUCTS INC	SICHUAN LONG MARCH PHARMACEUTICAL CO LTD, LESHAN, SICHUAN, CHINA - EIR 9/09 TO 9/11
2012-8814	12/11/2012 01/10/2013	OC/OM/OMP/DDM/	THOMAS FITZGERALD FSI RESEARCH & SERVICES, INC.	DKT 1976G-0445, 1977G-0049
2012-8815	12/11/2012 01/10/2013	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1976N-0052

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2012-8816	12/11/2012 01/10/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK SHARPE & DOHME CORP, WEST PT, PA - VACCINES & ALLERGENIC PRODUCTS; MERCK SERONO SPA, GUIDONIA MONTECELIO; MERCK SHARP & DOHME CORP, ELKTON, VA - VACCINES & ALLERGENIC PRODUCTS - RVWS, INSP
2012-8817	12/11/2012 01/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	MIKE SCHNEIDER BOOKHARDT & OTOOLE	KASEL, DENVER, CO - INSP12/11 TO PRESENT
2012-8818	12/11/2012 01/10/2013	FDA/OF/CFSAN/OCD/EOS/	D. GREGORY BLANKINSHIP MEISELMAN DENLEA ET AL	PLANT STEROLS - STUDIES
2012-8819	12/11/2012 01/10/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	SUSAN PRISET HARTLEY HAMPTON PC	SEMINAL EVENT RPT FILED BY MD ANDERSON RE INDIVIDUAL REC
2012-8820	12/11/2012 01/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	BRENTON L. HORNER HORNER & ASSOCIATES	CORR BETWEEN FDA & WORLD HEALTH PRODUCTS LLC
2012-8821	12/11/2012 01/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LAM, NELSON .	AGA MATRIX K103544
2012-8822	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	COCA-COLA - CAERS 1/04 TO PRESENT
2012-8823	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	PEPSI - CAERS 1/04 TO PRESENT
2012-8824	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	DR PEPPER - CAERS 1/04 TO PRESENT
2012-8825	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	MOUNTAIN DEW - CAERS 1/04 TO PRESENT
2012-8826	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	STARBUCKS COFFEE - CAERS 1/04 TO PRESENT
2012-8827	12/12/2012 01/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/	WEAVER, JOHN D	HEK293 - APRVL RECS, BRIEFING RECS

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		ALFB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/		
2012-8828	12/12/2012 01/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WEAVER, JOHN D	PER.C6 - APRVL RECS, BRIEFING RECS
2012-8829	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/	ROBERT S MCQUATE GRAS ASSOCIATES LLC	FCN 736
2012-8830	12/12/2012 01/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JASON SMITH BEDFONT SCIENTIFIC LTD	FIM MEDICAL - TABATABA CO TESTER CPT1200508 RECS
2012-8831	12/12/2012 01/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DOUG DIX UNIV OF HARTFORD	CANNABIS (MARIJUANA) - DRUG ENFORCEMENT APRVL RECS, FDA APRVL RECS
2012-8832	12/12/2012 01/11/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	MELINDA F LEVITT	NIH PROTOCOL 08-CH-0203 - EIR 10/11
2012-8833	12/12/2012 01/11/2013	FDA/OGROP/ORASW-FO/KAN- DO/KAN-CB/	Doe J	AFTERSHOCK TATTOO, OLATHE, KS - TATTOO RPT
2012-8834	12/12/2012 01/11/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER CONNER AMERICAN CLAIMS MANAGEMENT	PRIME ORTHOPEDICS (PRIME MEDICAL RESOURCES) - APPL, DVC LISTING REGISTRATIONS, LICENSING, ETC 1/03 TO 12/12
2012-8835	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	ROMAN LEBEDINSKIY TRAUB LIEBERMAN STRAUS ET AL	RAGE RV3, RAGE RV5, EPIO-PLEX, ETC - CORR, RECALL, RESP TO WARNING LTR, ETC 11/3/09
2012-8836	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	STEPHEN HELLER HELLER LAW FIRM	BETANCOURT NUTRITION INC - RIPPED JUICE EX2 CMLPTS, CAERS, COMM, ETC
2012-8837	12/12/2012 01/11/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA LOG (12/03/2012 - 12/07/2012)
2012-8838	12/12/2012 01/11/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	Robert M. Goldman CL King & Associates	HILL-ROM, INC, BATESVILLE, IN - 483 (08/10/2011 - 12/10/2012)
2012-8839	12/12/2012 01/11/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	Richard O. Wood the Wood Burditt group	LIBRARY INFORMATION BULLETIN 4434 2; ACTION LEVEL, TOLERANCE, OR GUIDANCE LEVEL FOR TETRACYCLINE IN HONEY

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2012-8840	12/12/2012 01/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring GRAY LTD	K955589, K010096, K110556
2012-8841	12/12/2012 01/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Suzanne O'Shea FAEGRE BAKER DANIELS	INO THERAPEUTICS - FORMS 3542 AND/OR 3542A RE NDA 20845 FOR PATENTS 8,291,904 AND 8,293,284; CORR
2012-8842	12/12/2012 01/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bernie Burgess BURGESS, BERNIE	IND 49105 GCP FILE 1840
2012-8843	12/12/2012 01/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stacy Woeppel B. Braun Medical Inc.	DIPRIVAN (NDA 019627) - QUALITY REVIEW
2012-8844	12/13/2012 01/14/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kelly A. Fitzpatrick The Lanier Law Firm	FRESENIUS MEDICAL CARE - GRANUFLO/NATURALYTE RECS, CORR, MDRS ETC
2012-8845	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 7702455-3
2012-8846	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Meyer ATS Labs	K120306
2012-8847	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Angela STagg IMPULSE DYNAMICS	SURESH NEELAGARU, AMARILLO, TX - EIR, 483 RESPONSE, FINAL DETERMINATION (10/10/2012 - 10/19/2012)
2012-8848	12/13/2012 01/14/2013	FDA/OF/CFSSAN/OCD/EOS/	Kevin D. Tucker EXPONENT	CONSULTATION DOCUMENT FOR MON 87460
2012-8849	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ATROVENT - MEDICAL OFFICER REVIEW
2012-8850	12/13/2012	FDA/OMPT/CDER/GRP/DIDP/	Shannon Pettypiece	RANBAXY, PUNJAB, IN - 483 2009, 2011; EIR 2000, 2003

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	01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BLOOMBERG NEWS	
2012-8851	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Michael C. Cotugno Cotugno, Michael C	DYNALABS, ST LOUIS, MO - 483 MOST RECENT
2012-8852	12/13/2012 01/14/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOETTE GIOVINCO MD WTVT FOX 13	KERATIN COMPLEX SMOOTHING THERAPY, KERATIN COMPLEX PRODUCTS - AERS, COMPLAINTS, MONITORING STUDIES
2012-8853	12/13/2012 01/14/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 527
2012-8854	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter A. Takes Kypha, Inc.	K981783
2012-8855	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Thomas W. Cooley Cooley, Thomas W	DYNALABS, ST LOUIS, MO - 483 (12/12/2011 - 12/11/2012)
2012-8856	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	John Fanikos Fanikos, John	DYNALABS, ST LOUIS, MO - 483 MOST RECENT
2012-8857	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA203214
2012-8858	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John Beasley MedTech Review, LLC	K100878
2012-8859	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Rachel Johnson FOI Services, Inc.	FRESCA FOODS, LOUISVILLE, CO - 483, WL
2012-8860	12/13/2012 01/14/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katie Thomas NEW YORK TIMES	RANBAXY - EIR, 483, CORR (01/01/2012 - 12/12/2012)
2012-8861	12/13/2012	FDA/OMPT/CDRH/OCER/DFOI/	ShaeAnn Cavanagh	K050228

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	01/14/2013		AGFA Healthcare	
2012-8862	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Danielle Starr Foster & Eldridge	IMPORTANT DRUG WARNING CONCERNING UNAPPROVED USE OF INTRAVAGINAL OR ORAL MISOPROSTOL IN PREGNANT WOMEN FOR INDUCTION OR LABOR OR ABORTION (08/23/00)
2012-8863	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K102461
2012-8864	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr. Diane Sudduth Biovance	K092191
2012-8865	12/13/2012 01/14/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Janice Gardner ood Safe Pacific LLC	GATE GOURMET, INC, HONOLULU, HI - EIR MOST RECENT (01/02/2012 - 12/12/2012)
2012-8866	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	Amy Shipley The Fort Lauderdale Sun-Sentinel	PHARMACIES IN FLORIDA - AERS, COMPLAINTS
2012-8867	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	MICHAEL ROYBAL ROYBAL GLOBAL	DYNALABS - 483 2010 TO 2012
2012-8868	12/13/2012 01/14/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MICHAEL ROYBAL ROYBAL GLOBAL	ANALYTICAL RESEARCH LABS - 483 2010 TO 2012
2012-8869	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	GLAXO SMITH KLINE - INFANRIX BL 103647 LBLG, APRVL, CHEM RVW
2012-8870	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	SANOFI PASTEUR - DALTACEL BL 103666 APRVL, LBLG, CHEM RVW
2012-8871	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	GLAXO SMITH KLINE - ENGERIX BL 103239 APRVL, LBLG, CHEM RVW
2012-8872	12/13/2012 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS Consulting Group, LLC	MERCK & CO - RECOMBIVAX HB BL 101066 APRVL, LBLG, CHEM RVW
2012-8873	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO, LANGENARGEN, GERMANY - EIR 7/12

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2012-8874	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	VETTER PHARMA FERTIGUNG GMBH & CO, RAVENSBURG, GERMANY -EIR 4/12
2012-8875	12/13/2012 01/14/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRENDA M. GARTZ ELI LILLY & CO	TECH GROUP, TEMPE, AZ - EIR 10/11
2012-8876	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	SANDOZ, KUNDL, AUSTRIA - EIR 8/12
2012-8877	12/13/2012 01/14/2013	FDA/OF/CFSAN/OCD/EOS/	PETER EISLER USA TODAY	PROTEIN POWDER/SHAKE FOR MUSTLE GROWTH - AER
2012-8878	12/13/2012 01/14/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL D. MARRS CONYBEARE LAW OFFICE P C	DR SYBESMA, LAKELAND REGIONAL HEALTH SYS - PLEXUR M BONE GRAFT AER
2012-8879	12/13/2012 01/14/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	WEDBUSH SECURITIES - FOI 1/10 TO PRESENT
2012-8880	12/13/2012 01/14/2013	ORA/ ORA/	ELCE M. ROGERS Dymatize Nutrition	CMPLNT 128733
2012-8881	12/13/2012 01/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAYLEE WHITE SALAMANDRA LLC	MEDWATCH 7853733, 7853742
2012-8882	12/13/2012 01/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	VINEET SARIN, PhD. KINAMED INC	KINAMED INC, CAMARILLO, CA - K032950, K010101, K994214 NON REDACTED
2012-8883	12/13/2012 01/14/2013	OC/OM/OMP/DDM/	JENNIFER PELAIA COVINGTON BURLING LLP	DKT FDA-2012-P-0904
2012-8884	12/13/2012 01/14/2013	FDA/OO/OFBA/OAGS/	Fay Barnes - IQ Solutions IQ Solutions	OFFICE OF WOMEN'S HEALTH RFTOP NATIONAL WOMEN AND GIRLS HIV/AIDS AWARENESS DAY 2013 - RFP, STATMENT OF WORK, MONTHLY REPORTS, ETC.
2012-8885	12/13/2012 01/14/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2012-8886	12/14/2012	FDA/OGROP/ORA/SE-FO/ATL-	Dustin Strickland	GREER LABORATORIES, INC, LENOIR, NC - COMPLAINT

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	01/15/2013	DO/ATL-CB/	GREER LABORATORIES, INC.	
2012-8887	12/14/2012	ORA/	Amy Shipley	FLORIDA PHARMACIES - INSPECTIONS 2009-2012;
	01/15/2013	ORA/	The Fort Lauderdale Sun-Sentinel	INFUPHARMA - INSPECTION RECS, CORR SINCE 7/30/12
2012-8888	12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Julie Donnelly	JUDGE ROTENBERG EDUCATIONAL CENTER, CANTON, MA
	01/15/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Boston Business Journal	- UNTITLED LETTER (05/23/2011)
2012-8889	12/14/2012	FDA/OMPT/CDER/GRP/DIDP/		SUPPRELIN LA IMPLANT - SIDE EFFECTS
	01/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Doe J	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2012-8890	12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue	K092141; K090519
	01/15/2013		Elevate Oral Care	
2012-8891	12/14/2012	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Dr. Paul Knoepfler	CELLTEX, RNL BIO, HUMAN BIOSTAR, ETC - APPROVAL RECS
	01/15/2013	FDA/OC/OES/DFOI/	UNIVERSITY OF CALIFORNIA, DAVIS	
2012-8892	12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Marcia L Zucker	K121679
	01/15/2013		ZIVD, LLC	
2012-8893	12/14/2012	FDA/OMPT/CTP/OD/	Ryan Meyer	HC0000048, HC0000067, HC0000068 ETC
	01/15/2013		HAGENS BERMAN SOBOL SHAPIRO LLP	
2012-8894	12/14/2012	ORA/		INDIVIDUAL RECS
	01/15/2013	ORA/	Doe J	
2012-8895	12/14/2012	FDA/OMPT/CDER/GRP/DIDP/	Tom Brakel	RELISTOR - AERS
	01/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Federated Investors	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2012-8896	12/14/2012	ORA/	Christy Wissman	WHITEWAVE FOOD, MOUNT CRAWFORD, VA - TEST RESULTS
	01/15/2013	ORA/	WhiteWave Foods	
2012-8897	12/14/2012	FDA/OF/CFSAN/OCD/EOS/	Nguyet Tran	USP LABS, LLC - WARNING LETTER (CERTIFIED)
	01/15/2013		Tran Law Offices	
2012-8898	12/14/2012	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Butterfield	K914190
	01/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Butterfield Technologies, LLC	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-8899	12/14/2012 01/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Heather Neely, Sr. Director RA/QA Kinamed, Inc.	KINAMED, INC, CAMARILLO, CA - UNREDACTED EIRS (05/25/1993 - 12/11/1997)
2012-8900	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K040985
2012-8901	12/14/2012 01/15/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/ FDA/OC/OES/DFOI/	Dale A. Scott Bell & Roper, P.A.	FOUR LOKO - GRAS REVIEW, CORR, SETTLEMENTS, ETC
2012-8902	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Lin Shoprider Mobility Products, Inc.	MW5027704 SHOPRIDER STREAMER SPORT POWER CHAIR MODEL 888WA - SERIAL NUMBER, DATES OF USE
2012-8903	12/14/2012 01/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alison Mann Stuebe UNC School of Medicine	ISR 6617751, 6902283, 7016471, ETC
2012-8904	12/14/2012 01/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alison Mann Stuebe UNC School of Medicine	DOMPERIDONE - FAERS
2012-8905	12/14/2012 01/15/2013	FDA/OF/CFSAN/OCD/EOS/	Dale A. Scott Bell & Roper, P.A.	PHUSION PROJECTS - CORR RE MANUFACTURE AND SALE OF ALCOHOLIC BEVERAGES CONTAINING CAFFEINE (11/13/09); CITY BREWING CO - CORR RE MANUFACTURE AND SALE OF ALCOHOLIC BEVERAGES CONTAINING CAFFEINE (11/13/09)
2012-8906	12/14/2012 01/15/2013	ORA/ ORA/ CVM/OCD/	Kristina Worsham Worsham, Kristina	DIAMOND PET FOODS, KIRKLAND, COSTCO - COMPLAINTS FILED IN COLORADO (01/01/2012 - 12/13/2012)
2012-8907	12/14/2012 01/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Donnelly Boston Business Journal	JUDGE ROTENBERG EDUCATIONAL CENTER - UNTITLED LETTER (06/29/2012)
2012-8908	12/14/2012 01/15/2013	ORA/OE/ ORA/OE/	George Ball UNIVERSITY OF MINNESOTA	MEDICAL DEVICE RECALL DATA (1994 TO PRESENT)
2012-8909	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN REEVES MAKO SURGICAL CORP	ORTHO SOFT INC -STEROTAXIC INSTRUMENT K071714
2012-8910	12/17/2012	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN REEVES	BLUE BELT TECHNOLOGIES -STEROTAXIC INSTRUMENTS K121936

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	01/16/2013		MAKO SURGICAL CORP	
2012-8911	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID WARNICK MARK A ADAMS LLC	BOSTON SCIENTIFIC - SPINAL CORD STIMULATOR FORM 3500A 9/1/10 TO 10/31/10
2012-8912	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEFFREY A ROWE MURPHY BUTTERFIELD & HOLLAND PC	LISITING OF MORPHINE PRODS 2002
2012-8913	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	GARDINER HARRIS NEW YORK TIMES	LUPIN LTD, BHOPAL, INDIA - 11/12/08; ZENOTHECH LABORATORIES LTD, ANDHRA PRADESH, INDIA - 1/21/09; STERICON PHARMA PVT LTD, BANGALOR, KARNATAKA, INDIA 3/17/10, ETC - EIRS, 483S, WARNING LTRS LISTED IN THE NDC DIRECTORY
2012-8914	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	SANDOZ INC - VORICONAZOLE (INJECTABLE IV INFUSION) NDA 90-0862, (TABLET ORAL) NDA 20-0265 CHEMISTRY RVWS
2012-8915	12/17/2012 01/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MICHAEL P KRENSAVAGE Krensavage Asset Management	RTI BIOLOGICS - 483
2012-8916	12/17/2012 01/16/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTER BROZOWISKI COKER SCHICKEL SORENSON ET AL	SANDOZ - PARENTA BRAND METHOTREXATE PROD RECALL 1/1/03 TO 12/12/12
2012-8917	12/17/2012 01/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	KATE WILLSON CENTER FOR PUBLIC INTEGRITY	RTI BIOLOGICS - 483 6/25/12 TO 7/11/12
2012-8918	12/17/2012 01/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWSDON PROJECT ON GOVERNMENT OVERSIGHT	HEALTH-CARE PROVIDERS - VAERS
2012-8919	12/17/2012 01/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWSDON PROJECT ON GOVERNMENT OVERSIGHT	SHINGLES PREVENTION STUDY - VAERS

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2012-8920	12/17/2012 01/16/2013	FDA/OF/CFSAN/OCD/EOS/	GARDINER HARRIS NEW YORK TIMES	VIET SPICES COMPANY LTD, MY PHUOC TOWN, VIETNAM - 9/21/10; INDIAN CHILLIES TRADING COMPANY LTD, VIRUDHUNAGAR, INDIA - 8/25/11; SWANI SPICE MILLS PVT LTD, NAVI MUMBAI, INDIA - 7/19/11, ETC - EIRS, 483'S, WARNING LTRS
2012-8921	12/17/2012 01/16/2013	FDA/OF/CFSAN/OCD/EOS/	BOBBY SHCHOCHET OLSSON FRANK WEEDA TERMAN BODE MATZ	INFANT FORMULA NOTIFICATION - CORR, MINS, EXHIBITS, ETC 6/1/12 TO PRESENT
2012-8922	12/17/2012 01/16/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-4541, 2012-4575, 2012-4694, ETC
2012-8923	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lakshmi Padmanabhan St.Jude Medical Neuromodulation	P840001/S076, P840001/S063, P960009/S035
2012-8924	12/17/2012 01/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Blowes Celgene Inc	NDA 022393 (ISTODAX) - CROSS DISCIPLINE TEAM LEADER'S REVIEW, MEDICAL REVIEW, STATISTICAL REVIEW, ETC
2012-8925	12/17/2012 01/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Julie M. Forte Ono Pharma, USA, Inc.	CBER BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE MEETING - PRESENTATION SLIDES (07/24/97)
2012-8926	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lakshmi Padmanabhan St.Jude Medical Neuromodulation	P970003/S065
2012-8927	12/17/2012 01/16/2013	FDA/OMPT/CTP/OD/	PAUL MENDOZA COMPANIA TABACALERA S.A	COMPANIA TABACALERA - LISTING OF INGREDIENTS IN TOBACCO PRODUCTS
2012-8928	12/17/2012 01/16/2013	FDA/OF/CFSAN/OCD/EOS/	Kerry King Intertox, Inc.	ODWALLA INCIDENT REPORT (10/30/96); PATHOGEN LEVELS OF LISTERIA IN APPLES (AUGUST 2012)
2012-8929	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tito Jankowski Self	K100040
2012-8930	12/17/2012 01/16/2013	FDA/OC/OES/DFOI/	Will Coggin CENTER FOR CONSUMER FREEDOM	ENVIRONMENTAL WORKING GROUP - FOIA REQUESTS (01/01/2012 - 12/14/2012)
2012-8931	12/17/2012 01/16/2013	ORA/ ORA/	Doe J	INDIVIDUAL RECS
2012-8932	12/17/2012 01/16/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS (11/22/2012 - 12/15/2012)
2012-8933	12/17/2012	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Bruce Metzger	DUTCHLAND FOODS, LESTER, IA - INSPECTION RECS (11/25/2012 - 12/15/2012)

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	01/16/2013		Bruce Metzger	
2012-8934	12/17/2012 01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ditza Auerbach ditza auerbach	K082268
2012-8935	12/17/2012 01/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/	Stephen Handal Independent	06/22/12 MEETING BETWEEN ELIZABETH DICKINSON AND KURT KARST - MEETING MINUTES, AMARIN RECS
2012-8936	12/17/2012 01/16/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (12/10/2012 - 12/14/2012)
2012-8937	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Holbert Clean Coating Technologies LLC	K101128
2012-8938	12/18/2012 01/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Janet McChristion Fresenius-kabi LLC USA	ANDA 079197, ANDA 200771, ANDA 202063, ETC - APPROVAL LTRS
2012-8939	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marie Getchell, Cre8MDI LLC Cre8MDI LLC	K070795
2012-8940	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marie Getchell, Cre8MDI LLC Cre8MDI LLC	K080670
2012-8941	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Steve Pardue Elevate Oral Care	K041482
2012-8942	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Marie Getchell, Cre8MDI LLC Cre8MDI LLC	K013434
2012-8943	12/18/2012 01/17/2013	ORA/ ORA/	Jen Wieczner Dow Jones/MarketWatch	DRUG PRODUCT CLASS I RECALLS (01/01/2005 - 12/17/2012)
2012-8944	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Traci S. Umberger PHYSIO-CONTROL, INC.	PHYSIO-CONTROL, INC - HEALTH HAZARD EVALUATION RE LIFEPAK 20, 20E
2012-8945	12/18/2012 01/17/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Traci S. Umberger PHYSIO-CONTROL, INC.	PHYSIO-CONTROL INC, REDMOND, WA - HEALTH HAZARD ANALYSIS, 483 10/24/12
2012-8946	12/18/2012	FDA/OGROP/ORA/SE-FO/FLA-	JoNel Aleccia	RTI BIOLOGICS, ALACHUA, FL - INSPECTION RECS,

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	01/17/2013	DO/FLA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	NBCNews.com	WARNING LETTERS, CORR (12/17/2005 - 12/17/2012)
2012-8947	12/18/2012 01/17/2013	OM/OMP/DODM/	Jennifer Brown (2642660) INFOTRIEVE	ORALLY INHALED/INTRANASAL CORTICOSTEROIDS AND GROWTH IN CHILDREN (1998)
2012-8948	12/18/2012 01/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Liliane A Patton Patton, Liliane A	FORTEO - AERS
2012-8949	12/18/2012 01/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	LARA WEISS GOLDBERG & GILLE LAW OFCS	FRANCK'S COMPOUNDING LAB, OCALA, FL - BRILLIANT BLUE G DYE RECS
2012-8950	12/18/2012 01/17/2013	OM/OMP/DODM/	MICHAEL G REIN WELDON-LINNE & VOGT	DERMATOLOGIC AND OPHTHALMIC DRUGS A/C - TRANS 9/19/00 (CERTIFIED)
2012-8951	12/18/2012 01/17/2013	FDA/OGROP/OIP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	CARMEN S SCOTT MOTLEY RICE LLC	MIRENA - AERS 1/09 TO PRESENT, CONTACT RPTS, LBLG, ETC
2012-8952	12/18/2012 01/17/2013	ORA/ ORA/	JOHN L HOLAHAN SIMPLY THICK LLC	SIMPLYTHICK PRODS - TEST RESULTS, SAMPLING
2012-8953	12/18/2012 01/17/2013	ORA/ ORA/	INGRID S MARTIN COLLORA LLP	NEW ENGLAND COMPOUNDING PHARMACY (NEW ENGLAND COMPOUNDING CENTER) - PROD SPLS TEST RESULTS
2012-8954	12/18/2012 01/17/2013	CVM/OCD/	Constance N. White DVM PhD Fremont Veterinary Clinic	ENALAPRIL (NADA 141015)
2012-8955	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K001948, K080670, K020537
2012-8956	12/18/2012 01/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	GREG L DREVENSTEDT PHD VALMONT RESEARCH LLC	DENTAL DVC IMPORTERS - 807.41 ESTABLISHMENT REGISTRATION AND DVC LISTING
2012-8957	12/18/2012 01/17/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	ALKERMES, WILMINGTON, OH - EIR 11/4/11
2012-8958	12/18/2012	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ	DSM PHARMS, GREENVILLE, NC - EIR 4/11

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	01/17/2013		ELI LILLY & CO	
2012-8959	12/18/2012 01/17/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	DSM PHARMS, GREENVILLE, NC - EIR 4/12
2012-8960	12/18/2012 01/17/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Traci Umberger PHYSIO-CONTROL, INC.	PHYSIO-CONTROL INC, REDMOND, WA - HEALTH HAZARD ANALYSIS, 483 (10/24/12)
2012-8961	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2010-7504, 2011-1983, 2011-5035, ETC
2012-8962	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-1613, 2012-1963, 2012-1976, ETC
2012-8963	12/18/2012 01/17/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-6067, 2012-6477, 2012-6663, ETC
2012-8964	12/19/2012 01/18/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	debra g speyer speyer, debra g	BAY IMAGING GROUP, NORTH FLORIDA - INSPECTION REPORTS, MQSA REVIEW, SUPERVISING PHYSICIAN, ETC (01/10/2008 - 12/31/2009)
2012-8965	12/19/2012 01/18/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ OM/OMP/DODM/	Thano Maceo Paris Thano Maceo Paris	GRADY HOSPITAL, ATLANTA, GA - INSPECTION, REPORT OF THE PUBLIC BOARD, TRANSCRIPT
2012-8966	12/19/2012 01/18/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Jennifer Szymanski Vitaflo USA	RENASTART - DISPOSAL OF RECALLED PRODUCT
2012-8967	12/19/2012 01/18/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	PHILIP MORRIS/ALTRIA - CORR RE L&M, MARLBORO NXT, MARLBORO SELECT KING SIZE (06/22/2009 TO PRESENT)
2012-8968	12/19/2012 01/18/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Gloria Candelario N/A	SAMPLE RESULTS
2012-8969	12/19/2012 01/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 8337594-X
2012-8970	12/19/2012	FDA/OC/OES/DFOI/	KEN REID	2011-708, 2012-5498, 2012-5584, ETC

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	01/18/2013		WASHINGTON INFORMATION SOURCE	
2012-8971	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-8193, 2012-8215, 2012-970, ETC
2012-8972	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-987, 2012-965, 2012-8187, ETC
2012-8973	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-5587, 2012-5496, 2012-8227, ETC
2012-8974	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2011-1471, 2012-967, 2012-5558, ETC
2012-8975	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-5517, 2012-964, 2012-5562, ETC
2012-8976	12/19/2012 01/18/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	2012-973, 2012-5683, 2012-8203
2012-8977	12/19/2012 01/18/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	CARDINAL HEALTH, COLTON, CA - EIR 12/11
2012-8978	12/19/2012 01/18/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	ANALYTICAL BIOCHEMISTRY LABS, COLUMBIA, MO - EIR 12/16/11
2012-8979	12/19/2012 01/18/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	BRENDA M GARTZ ELI LILLY & CO	BAXTER PHARMACEUTICAL SOLUTIONS, BLOOMINGTON, IN - EIR 9/12
2012-8980	12/19/2012 01/18/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JANICE M HOGAN HOGAN LOVELLS US LLP	SPINALMOTION INC - KINEFLEX C CERVICAL ARTIFICAL DISC P100011 PANEL HOMEWORK ASSIGNMENTS, RISK/BENEFIT W/S
2012-8981	12/19/2012 01/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA N WALLEN DELPHINUS MEDICAL TECHNOLOGIES INC	U-SYSTEMS INC, SUNNYVALE, CA - AUTOMATED BREAST ULTRASOUND SYS P110006 RECS
2012-8982	12/19/2012 01/18/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	BRENTON LORNER HORNER & ASSOCIATES	WORLD HEALTH PRODUCTS LLC - DETOXAMIN SUPPOSITORIES CORR, RESP TO LTR 12/12.11
2012-8983	12/19/2012 01/18/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KAREN ANDERSON WBZ-TV	SPECIALITY MINERALS INC - 7/24/12; PHARMALUCENCE INC - 4/25/12; AMAG PHARMACEUTICALS INC - 5/24/12, ETC 483S

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2012-8984	12/19/2012 01/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	AYAMI MARUYAMA CANON INC	REDIFORCE RX840-MG - K120451
2012-8985	12/19/2012 01/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB - AERS 1/10 TO PRESENT
2012-8986	12/19/2012 01/18/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Doe J	UNILEVER - WISHBONE SALAD DRESSING CMLNT
2012-8987	12/19/2012 01/18/2013	ORA/OE/ ORA/OE/ ORA/ORM/ ORA/ORM/ ORA/OE/ ORA/OE/	Kevin McCoy USA TODAY	FOOD FACILITIES, BOTTLED WATER PLANTS - LIST OF INSPECTIONS, RECALLS (07/18/2006 - 12/18/2012)
2012-8988	12/20/2012 01/22/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	OCTAPharma PLASAM INC, VIRGINIA BEACH, VA - EIR, 483 2/3/12
2012-8989	12/20/2012 01/22/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MIRAMAR COSMETICS INC, DORAL, FL - EIR, 483 1/3/12
2012-8990	12/20/2012 01/22/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	EXPERT CHEMICAL ANALYSIS INC, SAN DIEGO, CA - EIR, 483 1/28/11
2012-8991	12/20/2012 01/22/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	ALK ABELLO INC, PORT WASHINGTON, NY - 3/21/12
2012-8992	12/20/2012 01/22/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PETNET SOLUTIONS, KENT, WA - EIR, 483 2/12
2012-8993	12/20/2012 01/22/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	JUBILANT CADISTA PHARMACEUTICALS, SALISBURY, MD - EIR, 483 3/14-23/12
2012-8994	12/20/2012 01/22/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TISSUE BANKS INT'L, MEMPHIS, TN - EIR, 483 6/18-20/12
2012-8995	12/20/2012 01/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	SHANGHAI HUHUI DAILY USE CHEMICAL PRODUCTS, SHANGHAI, CHINA - EIR, 483 2/6-10/12

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2012-8996	12/20/2012 01/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SALEM HOSPITAL IRB, SALEM, OR - EIR, 483 6/6-25/12
2012-8997	12/20/2012 01/22/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	RTI BIOLOGICS INC, ALACHUA, FL - EIR, 483 6/26-7/11/12
2012-8998	12/20/2012 01/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RUTH RIZKALLA, Esq. SIZEMORE LAW FIRM PLC	rhBMP-2 - LICENSE APPLICATION
2012-8999	12/20/2012 01/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALEX VEIZIS FDALIVE.COM	CHDR ADVISORY COMMITTEE MTG
2012-9000	12/20/2012 01/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	JURGEN KALBER MEDENTIKA GMBH.	TI BASE ABUTMENT - NT TRADING GMBH AND CO KG, CLAREMONT, NH - K111935
2012-9001	12/20/2012 01/22/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/	GISSENDANNER, ROBIN	CMPLNT 120110
2012-9002	12/20/2012 01/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW 017561, JOHN	SELENIUM SULFIDE LOTION; GELENIOM SOLFIDE TOPICAL SUSPENSION - RECALL
2012-9003	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	JH BARR & ASSOCIATES LLC	DAILY LOG 11/26-30/12
2012-9004	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 11/19-23/12
2012-9005	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/10-14/12
2012-9006	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/3-7/12
2012-9007	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/3-7/12

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2012-9008	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/10-14/12
2012-9009	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 12/3-7/12
2012-9010	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA WEBVIEW/FERDIC INC	DAILY LOG 12/10-14/12
2012-9011	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/3-7/12
2012-9012	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/10-14/12
2012-9013	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/10-14/12
2012-9014	12/20/2012 01/22/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/3-7/12
2012-9015	12/21/2012 01/23/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Lelia M. Fuentes CARDINAL HEALTH	POSITRON EMISSION TOMOGRAPHY DRUG MANUFACTURERS - EIRS(12/31/2010 - 12/31/2012)
2012-9016	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K090700
2012-9017	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K974651
2012-9018	12/21/2012 01/23/2013	FDA/OF/CFSAN/OCD/EOS/	Lena Gomez Keller and Heckman, LLP	CAFFEINE INTAKE BY THE US POPULATION
2012-9019	12/21/2012	FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER	INCIVEK - AERS

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	01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dow Jones & Company	
2012-9020	12/21/2012 01/23/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/ FDA/OC/OES/DFOI/	Emily Bartkowicz AKERMAN SENTERFITT ATTYS	TOPICAL ANTIFUNGAL DRUG PRODUCTS FOR OTC HUMAN USE - MEDICAL LITERATURE, JOURNALS, TESTING, ETC; KRAMER LABORATORIES, KRAMER CONSUMER HEALTHCARE - CORR WITH FDA
2012-9021	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Bulls TECHLAB, Inc.	K093295
2012-9022	12/21/2012 01/23/2013	FDA/OF/CFSAN/OCDE/EOS/	Leslie H. Joyner, Esq. Marlin & Saltzman	HANSEN'S PREMIUM DIET SODA WITH ALL NATURAL FLAVORS - ALL RECS
2012-9023	12/21/2012 01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	WELLSPRING, ONTARIO, CANADA - QAP
2012-9024	12/21/2012 01/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Dominique Huff Home Rule News	PLASMA DONATION - STATISTICAL DATA
2012-9025	12/21/2012 01/23/2013	FDA/OO/OFBA/OAGS/	Reindeer Charities Goedert, Matthew D	STOP GRANTS - JOIN TOGETHER NORTHERN NEVADA APPLICATION
2012-9026	12/21/2012 01/23/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Alexandra Ajmo LIFE EXTENSION	LIFE EXTENSION, NATURE'S VALUE INC, GEMINI PHARMACEUTICALS, ETC - EIRS
2012-9027	12/21/2012 01/23/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	RO Wood the Wood Burditt group	PRESERVATION SOLUTIONS INC, ELKHORN, WI - 483, 482, EIR ETC
2012-9028	12/21/2012 01/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendell Tong Tong, Wendell	STYKER REJUVENATE, STRYKER ABG - SUBMITTED RECS, REVIEWS, ADVERSE EVENTS ETC
2012-9029	12/21/2012	FDA/OMPT/CDER/GRP/DIDP/		PREDISONE, ONCOVIN, MECHLORETHAMINE HCL, ETC - MFRS ADDRESS, DRUG INTERACTION RECS 1981 TO 1985,

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	01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CRISSEP #1258732, KENNETH	ETC
2012-9030	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	AVASTIN (BEVACIZUMAB) INJ, MIAMI-DADE COUNTY, FL - RECS 7/11
2012-9031	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/8-12/12
2012-9032	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/1-5/12
2012-9033	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/15-19/12
2012-9034	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/22-26/12
2012-9035	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 10/29/12-11/2/12
2012-9036	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/5-9/12
2012-9037	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/12-16/12
2012-9038	12/21/2012 01/23/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/19-23/12
2012-9039	12/21/2012 01/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN MANCINI ARIZONA STATE HOSPITAL	DECADRON PHOSPHATE INJ, DEXAMETHASONE SODIUM PHOSPHATE INJ - AERS
2012-9040	12/21/2012 01/23/2013	FDA/OGROP/ORP/SE-FO/FLA-DO/FLA-CB/ ORA/OCI/ ORA/OCI/	Anderson, Carl	GAVIN SMITH, PRECISION PEPTIDES, LUTZ, FL - SALE OF PEPTIDES, ANABOLIC STEROIDS, HUMAN GROWTH HORMONE COMM 1/11 TO PRESENT

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2012-9041	12/21/2012 01/23/2013	CVM/OCD/	Douglass Oeller Douglass Oeller Consulting, Inc.	AAFCO FEED INGREDIENT DEFINITION FOR USE OF L-CARNITINE IN MILK REPLACER FOR RUMINANTS - STUDY DESIGN
2012-9042	12/21/2012 01/23/2013	CVM/OCD/	Douglass Oeller Douglass Oeller Consulting, Inc.	AAFCP FEED INGREDIENT DEFINITION FOR THE USE OF CHROMIUM PROPIONATE IN CATTLE FEED - STUDY DESIGN
2012-9043	12/21/2012 01/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Dow Jones & Company	ARANESP - AERS
2012-9044	12/21/2012 01/23/2013	OC/OM/OCIO/ FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2012-9045	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7936 REQUEST LETTER
2012-9046	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8010 REQUEST LETTER
2012-9047	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7971 REQUEST LETTER
2012-9048	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7903 REQUEST LETTER
2012-9049	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8034 REQUEST LETTER
2012-9050	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8045 REQUEST LETTER
2012-9051	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8090 REQUEST LETTER
2012-9052	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7085
2012-9053	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8041 REQUEST LETTER
2012-9054	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8245 REQUEST LETTER
2012-9055	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8295 REQUEST LETTER

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2012-9056	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8367 REQUEST LETTER
2012-9057	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8457 REQUEST LETTER
2012-9058	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8481 REQUEST LETTER
2012-9059	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8338 REQUEST LETTER
2012-9060	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8333 REQUEST LETTER
2012-9061	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7476
2012-9062	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7066
2012-9063	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7065
2012-9064	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7058
2012-9065	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6664
2012-9066	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7566
2012-9067	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-3744
2012-9068	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8159
2012-9069	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7573
2012-9070	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5150
2012-9071	12/26/2012 01/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8360
2012-9072	12/26/2012	FDA/OGROP/ORACE-FO/CHI-	Ed Yoo	PHELPS INDUSTRIES - VIOLATIONS; SANCTIONS

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	01/25/2013	DO/CHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Corporate Resolutions Inc.	(12/19/2002)
2012-9073	12/27/2012 01/28/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Tim Kelly BIOLIFE	K021062
2012-9074	12/27/2012 01/28/2013	ORA/ ORA/ ORA/OE/ ORA/OE/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ ORA/OE/ ORA/OE/	Jen Wieczner Dow Jones/MarketWatch	DRUG RECALLS - LIST BEFORE CLASSIFICATION
2012-9075	12/27/2012 01/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Susan Winokur Winokur, Susan	HI-TECH PHARMACAL - BIOEQUIVALENCE STUDY AND RATING FOR LEVOCARNITINE
2012-9076	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8462
2012-9077	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8235
2012-9078	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8080
2012-9079	12/27/2012 01/28/2013	ORA/ ORA/	Jeremy Finley WSMV-TV	FOREIGN OBJECTS IN FOOD - COMPLAINTS IN TENN
2012-9080	12/27/2012 01/28/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Leslie H. Joyner Esq. Marlin & Saltzman	OH SO CLEAN, CLEANWELL PRODUCTS - CONSUMER COMPLAINTS (10/25/2008 - 12/20/2012)
2012-9081	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Sandy Stagge CTI Clinical Trial & Consulting	HILLARD LAZARUS, CINCINNATI, OH - 483, CORR (08/01/1997 - 10/29/1997)

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			Services	
2012-9082	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	UNIVERSITY HOSPITAL CASE MEDICAL CENTER IRB, CLEVELAND, OH - 483, CORR (11/30/2011 - 01/31/2012)
2012-9083	12/27/2012 01/28/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Richard P. Dickey, MD, PhD The Fertility Institute of New Orleans	IVF CLINICS - FDA DISASTER RESPONSE INSPECTION REPORTS (10/21/12-10/30 2012)
2012-9084	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Richard P Dickey, MD, PhD Fertility Institute of New Orleans	FDA DISASTER RESPONSE INSPECTIONS OF IVF CLINICS (10/21/12-10/30/12)
2012-9085	12/27/2012 01/28/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Leslie H. Joyner, Esq. Marlin & Saltzman	NONGSHIM PRODUCTS - RECALLS, INSPECTIONS, ADVERSE EVENTS, ETC (12/19/2008 - 12/21/2012)
2012-9086	12/27/2012 01/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rowena Dodaro ALKERMES INC	VIVOTROL - 8379054-6, 8453511-6
2012-9087	12/27/2012 01/28/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Leslie H. Joyner, Esq. Marlin & Saltzman	DIET 7UP - RECALL RECS, INSPECTION RECS, AERS, ETC (01/05/2009 - 12/21/2012)

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		FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/		
2012-9088	12/27/2012 01/28/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG (12/17/2012 - 12/21/2012)
2012-9089	12/27/2012 01/28/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristina Farmer Segal McCambridge Singer & Mahoney	MERIX PHARMACEUTICAL, BARRINGTON, IL - ALL RECS
2012-9090	12/27/2012 01/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mira Parekh UCSF Medical Center	LAMOTRIGINE - AERS
2012-9091	12/27/2012 01/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Evens Augustin Evens Augustin	K122356, K113514, K110704
2012-9092	12/28/2012 01/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Mathieu PAREXEL International Corp.	IND DATA
2012-9093	12/28/2012 01/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Munjai Sheladia PureTek Corporation	NDA 017010; ANDA 072354 - SUMMARY BASIS OF APPROVAL
2012-9094	12/28/2012 01/29/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Yvonne Higgins COPERNICUS GROUP IRB	COPERNICUS GROUP IRB, DURHAM, NC - 483, EIR (03/10)
2012-9095	12/28/2012 01/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rennae Lalwor Peninsula Regional Medical Center	XALERO - AERS (01/01/2012 - 12/26/2012)

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2012-9096	12/28/2012 01/29/2013	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	FUNDING ALLOCATED FOR OMS AWARDS; AWARD PROCEDURES; AWARD CORRESPONDENCE, ETC (01/01/2008 - 12/20/2012)
2012-9097	12/28/2012 01/29/2013	FDA/OC/OES/DFOI/	LaVeeta Moten LaVeeta Moten	INDIVIDUAL RECS
2012-9098	12/28/2012 01/29/2013	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	REGULATION, POLICY, DIRECTIVE RE: SELECTION OF STAFF TO REVIEW RESUMES FOR GS-13 DETAILS AND PROMOTIONS WITHIN OMS; CORR RE: REVIEW OF APPLICATIONS OR RESUMES
2012-9099	12/28/2012 01/29/2013	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	CFSAN BIRS SYSTEM - USE OR CORR RE NON-USE (01/01/2008 - 12/20/2012)
2012-9100	12/28/2012 01/29/2013	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	CFSAN OSM - EMPLOYEE GRADE, TITLE, PROJECTS, ETC (01/01/2008 - 12/20/2012)
2012-9101	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	KALYDECO - AERS
2012-9102	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	BG-12 - AERS
2012-9103	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	XTANDI - AERS
2012-9104	12/28/2012 01/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	KYPROLIS - AERS
2012-9105	12/28/2012 01/29/2013	OC/OM/OMP/DDM/	JANNA DEPORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	DKT & DKT LOG OF 1999P-2630
2012-9106	12/31/2012 01/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	RHOGAM - VAERS (01/20/2009 - 12/28/2012)

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2012-9107	12/31/2012 01/30/2013	CVM/OCD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	POLYSORBATE 80 - 05/21/08 LETTER FROM CVM
2012-9108	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG (12/24/2012 - 12/28/2012)
2012-9109	12/31/2012 01/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	EFUDEX - AERS
2012-9110	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	michael reilly integrity bio	DMF 12053 (LYOJECT)
2012-9111	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carl O. Magnell Valmed, S.A.	1000 MUSCLE STIMULATOR SYSTEM - 510K
2012-9112	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Luk Van Hecke TERUMO EUROPE NV	SYRINGE PUMP - MAUDE REPORTS (01/01/2012 - 12/27/2012)
2012-9113	12/31/2012 01/30/2013	ORA/ ORA/	Amandeep Singh RiaFragranceIncDBANaturalHoneyI mporters	SAMPLE RESULTS
2012-9114	12/31/2012 01/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Samuel Graham University of Wisconsin-Milwaukee	NDA 21446 S010
2012-9115	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/5-9/12
2012-9116	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 11/12-16/12
2012-9117	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12-3-7-12
2012-9118	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 12/3-7/12
2012-9119	12/31/2012	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	FOI DAILY LOG 11/26-30/12

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	01/30/2013		CanReg, Inc.	
2012-9120	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/3-7/12
2012-9121	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 11/26-30/12
2012-9122	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/3-7/12
2012-9123	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 11/26-30/12
2012-9124	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/3-7/12
2012-9125	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 11/26-30/12
2012-9126	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 11/26-30/12
2012-9127	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 12/3-7/12
2012-9128	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 11/26-30/12
2012-9129	12/31/2012 01/30/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/3-7/12
2012-9130	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	L LEE HICKS II MOORE & HICKS PC	ENCORE ORTHOPEDICS INC - TIBIAL INSERT K963028
2012-9131	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	L LEE HICKS II MOORE & HICKS PC	ENCORE ORTHOPEDICS INC - FOUNDATION KNEE SYS TIBIAL COMPONENT K970031
2012-9132	12/31/2012 01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	JULIE VAFIDES DEPUY MITEK	DEPUY MITEK - INTRAFIX TAPERED SCREW (INTRATUNNEL FIXATION FASTENER) K983560
2012-9133	12/31/2012 01/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROTH, GAIL P	ABILIFY - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2012-9134	12/31/2012 01/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	DAVID C WEBER BEHREND ERNSBEERGER, PC	ROXANE LABS - PREDNISONE CITIZEN PETITIONS, PI, MEDICAL JOURNAL RPTS 1999 TO PRESENT
2012-9135	12/31/2012 01/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HELEY 56354-112, FRANK	ELAVIL - AERS
2012-9136	12/31/2012 01/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S WALLER SEATTLE GENETICS INC	ADCETRIC (BRENTUXIMAB VEDOTIN) - AERS 3/1/12 TO 11/30/12
2012-9137	12/31/2012 01/30/2013	FDA/OF/CFSAN/OCD/EOS/	LISA Y LEFFERTS CENTER FOR SCIENCE IN PUBLIC INTEREST	BROMINATED VEGETABLE OIL - TOXICOLOGICAL STUDIES, TOXICITY CORR, AERS 1/70 TO PRESENT
2012-9138	12/31/2012 01/30/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CARES 159466 - ADDITIONAL RECS
2012-9139	12/31/2012 01/30/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159466 - ADDITIONAL RECS
2013-1	01/02/2013 01/31/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER CONNER AMERICAN CLAIMS MANAGEMENT	PRIME ORTHOPEDICS INC, PRIME MEDICAL RESOURCES - 483S, MDRS, ESTABLISHMENT REGISTRATION, ETC
2013-2	01/02/2013 01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/ FDA/OC/OES/DFOI/	LOUIS S FRANECKE FRANECKE LAW GROUP	ST JUDE MEDICAL - RIATA, RIATA ST DEFIBRILLATION P950022/S006,S007,S008, ETC EIRS, 483S, RPTS, ETC
2013-3	01/02/2013 01/31/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Meade, Doris	GM MANUFACTURING INC, GARDENA, CA - 483S 1/23/12- 2/13/12
2013-4	01/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	RANDY SCHERER PHD	MERIT MEDICAL INC - EMBOSPHERE MICROSPHERES

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	01/31/2013		Cook Medical	INVESTIGATIONAL DVC EXEMPTION (IDE) APRVL LTR, PHASE III CLNCL STUDY PROTOCOL
2013-5	01/02/2013 01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	HENSON, JOHN. D	MEDTRONIC - INSULIN PUMP P980022 RECS
2013-6	01/02/2013 01/31/2013	FDA/OF/CFSAN/OCD/EOS/	BETH CLAY CAPITOL STRATEGY CONSULTANTS	DIETARY SUPPLEMENTS - FDA REGISTRY DATA
2013-7	01/02/2013 01/31/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/OM/OMP/DODM/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	ALYSON OLIVER OLIVER LAW GROUP	PHARMACEUTICAL INNOVATIONS INC - ULTRA PHONIC CONDUCTIVITY GEL, SONIC GENERIC ULTRASOUND TRANSMISSION GEL, ULTRA PHONIC FONTANELLE SCANNING PAD, ETC INSP, LBLG, STERILIZATION, ETC
2013-8	01/02/2013 01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ALYSON OLIVER OLIVER LAW GROUP	MEDTRONIC - MOSAIC PROCINE BIOPROSTHETIC HEART VALVE PMA, RVWS, PROCEDURE MANUALS, ETC
2013-9	01/02/2013 01/31/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	DOUGLAS N BLUE II ZETETIC	BEINING NOVARTIS PHARMA CO LTD - COARTEM 120 MG ENTRY #112-6851042-1 REFUSAL RECS
2013-10	01/02/2013 01/31/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE II ZETETIC	AV300384441 - RECS
2013-11	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATY MORTON TOPICA PHARMACEUTICALS INC	KATAYAMA SEIYAKUSHYO CO LTD, TOYAMA, JAPAN - EIRS, 483S, WARNING LTRS, ETC 1/04 TO PRESENT
2013-12	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM BRENNAN SEDGWICK LLP	COVIDIEN - ONYX LIQUID EMBOLIC SYS (ONYX HD-500) AERS
2013-13	01/02/2013 01/31/2013	FDA/OF/CFSAN/OCD/EOS/	CHRISTIE L GARZA ARMANDO DE DIEGO PC	FDA RETAIL AND FOOD SERVICE HACCP, FDA SEAFOOD HACCP 5/03 (CERTIFIED)

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2013-14	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	KATY MORTON TOPICA PHARMACEUTICALS INC	KATAYAMA SEIYAKUSHYO CO LTD, OSAKA, JAPAN - EIRS, 483S, WARNING LTRS, ETC 1/04 TO PRESENT
2013-15	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KARRAS, EDWARD	ACTOS, METFORMIN, PIOGLITAZONE - RECS
2013-16	01/02/2013 01/31/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ ORA/OCI/ ORA/OCI/	Anderson, Carl	DANIEL LANSDOWN, PURE PEPTIDES, HOUSTON, TX - ANABOLIC STEROIDS, HUMAN GROWTH HORMONE CORR 1/10 TO PRESENT
2013-17	01/02/2013 01/31/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	RUTH RIZKALLA ESQ SIZEMORE LAW FIRM PLC	RHBMP-2 - BIOLOGICS, DRUG LICENSE APPL
2013-18	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREWS D17561, JOHN	MORTON GROVE - SELENIUM SULFIDE LOTION; PERRIGO - SELENIUM SULFIDE TOPICAL SOL RECALL RECS
2013-19	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 202608 - APPROVAL LETTER
2013-20	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	NDA 202292 - APPROVAL PACKAGE
2013-21	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen R. Auten COZEN O'CONNOR	ANDA 202093 - FILING RECEIPT, CORR, PATENT CERTIFICATIONS ETC
2013-22	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	RONALD A. MARRON LAW OFFICES OF RONALD A MARRON	UNDREDACTED RECS

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2013-23	01/02/2013 01/31/2013	ORA/ORM/ ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	ALL NOTICES TO PHARMACEUTICALS - 483'S 11/12
2013-24	01/02/2013 01/31/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	SINEAD O'DONOGHUE GLOOR LAW GROUP LLC	ROLFS PATISSERIE, LINCOLNWOOD, IL - S AUREUS OUTBREAK SINCE 11/2/10
2013-25	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	RANBAXY, BATAMANDI - EIR 3/08
2013-26	01/02/2013 01/31/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	REZA TORKZADEH TORKZADEH LAW FIRM	PMA P950022
2013-27	01/02/2013 01/31/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK - ZOSTAVEX SHINGLES PATIENTS
2013-28	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY D. ERNST COREPHARMA LLC	SANOFI - DIABETA NDA 17-532 SBA
2013-29	01/02/2013 01/31/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	VICTORIA SCOTT HEMISPHERX BIOPHARMA	HEMISPHERX BIOPHARMA INC, NEW BRUNSWICK, NJ - INSP CORR 10/12, 11/12
2013-30	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	REO TANOSHIMA, MD HOSPITAL FOR SICK CHILDREN	KEPPRA - AER
2013-31	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SPENCER D29593, NATHAN	SEROQUEL - AER 2000 TO 2008
2013-32	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS T67081, KEITH	CANNABINOIDS - APRVL RPT
2013-33	01/02/2013 01/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HENLEY 56354 112, FRANK	EFFEXOR - AER

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2013-34	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (12/01/2012 - 01/02/2013)
2013-35	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LIST OF CLOSED FOIA REQUESTS (1/1/2012 - 12/31/2012)
2013-36	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	LIST OF CLOSED FOIA REQUESTS (12/1/12-12/31/12)
2013-37	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG (12/1/12-12/31/2012)
2013-38	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 12/10-14/12
2013-39	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 12/17-21/12
2013-40	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/17-21/12
2013-41	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/10-12/12
2013-42	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/10-14/12
2013-43	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/17-21/12
2013-44	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/10-14/12
2013-45	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/17-21/12
2013-46	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/10-14/12
2013-47	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 12/17-21/12
2013-48	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/17-21/12

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2013-49	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/10-14/12
2013-50	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/10-14/12
2013-51	01/02/2013 01/31/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/17-21/12
2013-52	01/03/2013 02/01/2013	OC/OM/OMP/DDM/	MINDY B. DUANE INFOTECH DATA RESEARCH	DKT FDA- 1995-S-0039
2013-53	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/17-21/12
2013-54	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 12/17-21/12
2013-55	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	LISA TARISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/17-21/12
2013-56	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS12/17-21./12
2013-57	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/17-21/12
2013-58	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	CLOSED FOIA REQUESTS 11/26-30/12
2013-59	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	CLOSED FOIA REQUESTS 12/3-7/12
2013-60	01/03/2013 02/01/2013	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	BRENDA M GARTZ ELI LILLY & CO	CARDINAL HEALTH, ORLANDO, FL - EIR 3/11
2013-61	01/03/2013 02/01/2013	FDA/OGROP/OR/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	HOSPIRA, MCPHERSON, KS - EIR 1/12, 5/12
2013-62	01/03/2013 02/01/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	MUSTAFA NEVZAT, YENIBONSNA, TURKEY - EIR 4/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-63	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	MUTSAFA NEVZAT LLAC SANAYII, ISTANBUL, TURKEY - EIR 11/10
2013-64	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	BRENDA M GARTZ ELI LILLY & CO	NORBROOK LABS, NEWRY, GB - EIR 4/12
2013-65	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	ORION CORP, ESPOO, FINLAND - EIR 6/11
2013-66	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAE WU NATURAL RESOURCES DEFENSE COUNCIL	COLGATE-PALMOLIVE - NDA 02-0231 RVWS, PHARMACOLOGY, TOXICOLOGY RECS
2013-67	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	IMPAX - ANDA 76-298 APRVL LTR
2013-68	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CASSELLS, KEITH	AVANDIA - AERS
2013-69	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	SEAN HIGGINS ANDREWS THORNTON	JACK3D, OXYELITE PRO, NUTREX LIPO-6 BLACK PRODS, ETC - AERS 5/12 TO PRESENT
2013-70	01/03/2013 02/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT	MERCK SHARP & DOHME - ZOSTAVAX NDA 12-5123 ANNUAL RPTS 12/30/09, 6/18/12

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			OVERSIGHT	
2013-71	01/03/2013 02/01/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/	SHANNA DEVINE GOVERNMENT ACCOUNTABILITY PROJECT	CRUDE OIL, COREXIT 9500, COREXIT 9527 - TRANS, INTERVIEWS, STATEMENTS, ETC 4/20/10 TO 1/26/12
2013-72	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	YOIRA FERNANDEZ FREIDIN DORBRINSKY ATTY AT LAW	2012-6312 (CERTIFIED)
2013-73	01/03/2013 02/01/2013	ORA/ ORA/	Doe J	CMPLNT
2013-74	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202379 S5
2013-75	01/03/2013 02/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD O DEROBERTS DEROBERTS, RICHARD O	K111501
2013-76	01/03/2013 02/01/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Rachel Nosowsky UNIVERSITY OF CALIFORNIA	COLUMBIA PRESBYTERIAN MEDICAL CENTER, NEW YOR, NY - 483, EIR, CORR (01/01/2011 - 01/01/2013)
2013-77	01/03/2013 02/01/2013	FDA/OF/CFSAN/OCD/EOS/	Michelle Minton The Competitive Enterprise Institute	DIET COKE, MOUNTAIN DEW, COCA COLA, ETC - AERS (01/01/08 TO 01/01/13)
2013-78	01/03/2013 02/01/2013	OM/OMP/DODM/	Dan Litvin Garwin, Gerstein & Fisher LLP	DKT 2007-P-011, 2008-D-0369 (CERTIFIED)
2013-79	01/03/2013 02/01/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENT TOBACCO INFORMATION
2013-80	01/03/2013 02/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dolly Mistry COVIDIEN	K954300
2013-81	01/03/2013 02/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125084 S153
2013-82	01/03/2013 02/01/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Kara Morgenstern UNIVERSITY OF MICHIGAN	COLUMBIA PRESBYTERIAN HOSPITAL, NEW YORK, NY - 483 (07/01/2012 - 08/31/2012)
2013-83	01/03/2013 02/01/2013	ORA/OE/ ORA/OE/	WIEJIA DAI University of Maryland, College Park	MEDICAL DEVICE RECALL DATA (06/01/1976 - 12/31/2012)

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2013-84	01/03/2013 02/01/2013	CVM/OCD/	Julie putnam NBC UNIVERSAL	JERKY PET TREAT INSPECTIONS - VIDEOS, PHOTOS, ETC (MARCH/APRIL 2012)
2013-85	01/03/2013 02/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Thomas Perls MD, MPH BOSTON UNIVERSITY SCHOOL OF MEDICINE	GENOTROPIN, NORDITROPIN, NUTROPIN, ETC -ANNUAL DISTRIBUTION DATA REPORTS
2013-86	01/03/2013 02/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Steve Auten COZEN O'CONNOR	VALSARTAN FORFEITURE MEMO
2013-87	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	INDIVIDUAL RECS
2013-88	01/03/2013 02/01/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	INDIVIDUAL RECS
2013-89	01/04/2013 05/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	GARCIA JR, NARCISO	INDIVIDUAL RECS
2013-90	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL W ERNSBERGER ESQ BEHREND ERNSBEERGER, PC	BARD ACCESS SYSTEMS INC - POWER PICC CATHETERS MDRS
2013-91	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	DAMON 4CLEAR K081415
2013-92	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	EMPOWER CLEAR K122753
2013-93	01/04/2013 02/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	HELEN LEWIS DENTSPLY INTERNATIONAL	CLARITY MODIFIED CERAMIC BRACKETS K062305
2013-94	01/04/2013 02/04/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 150606, 150166
2013-95	01/04/2013 02/04/2013	FDA/OF/CFSAN/OCD/EOS/	Doe J	RED BULL, 5 HOUR ENERGY, MONSTER, ROCKSTAR ENERGY DRINKS - CAERS

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2013-96	01/04/2013 02/04/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	INDIVIDUAL RECS
2013-97	01/04/2013 02/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	ISRS 8255707, 8439906, 8444371, ETC
2013-98	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121876
2013-99	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K020791
2013-100	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090435
2013-101	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deb Hogerman UCB, Inc.	NDA 21829 S 001, 002
2013-102	01/07/2013 02/05/2013	FDA/OF/CFSAN/OCD/EOS/	Becky Cooseman Brown & Crouppen, PC	MEAD JOHNSON NUTRITION - REPORTABLE FOOD REGISTRY REPORTING (01/01/2002 - 01/03/2013)
2013-103	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Laird Forrest HylaPharm	ABRAXANE IND - 505(B)(2) APPLICATION
2013-104	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Karin Desjardins COVIDIEN	K962577
2013-105	01/07/2013 02/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dan Litvin Garwin, Gerstein & Fisher LLP	ANDA 090596, 090402, 091195 ETC - SBA
2013-106	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	QiuHu Shi NEW YORK MEDICAL COLLEGE	K051672, K072625, K102159
2013-107	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Weisman, Kennedy & Berris	K003363

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2013-108	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	SILICONE, GEL-FILLED AND SALINE BREAST IMPLANTS - CLNCL TRIALS, REGULATIONS
2013-109	01/07/2013 02/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK - ZOSTAVAX SHINGLES PREVENTION STUDY SUMMARY MASTER FILE; BIOLOGICAL LICENSE APPL (BLA)
2013-110	01/07/2013 02/05/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DOMESTIC AND FOREIGN INSPECTIONS, 11/1-30/12, DRUG COMPANIES, MDM, BIMO AND GLP
2013-111	01/07/2013 02/05/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Laird Forrest HylaPharm	XALKORI - ORPHAN DRUG DESIGNATION
2013-112	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Philip William Blair Self	CRESTOR - AERS
2013-113	01/07/2013 02/05/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/	NICOLE C. ANDERSEN KREINDLER & KREINDLER	ENERGY DRINKS, DAWN RPT 11/22/11
2013-114	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric H. Weinberg, Esq. Law Firm of Eric H. Weinberg	NDA 22512 S011
2013-115	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	MALLINKRODT INC - METHYLPHENIDATE HCL ANDA 202-608 APRVL LTR 12/28/12
2013-116	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ OM/OMP/DODM/ FDA/OMPT/CDRH/OCER/DFOI/	AudismFreeAmerica Audism Free America	EFFICACY OF COCHLEAR IMPLANTATION WITH YOUNG DEAF CHILDREN - REPORT OF EXPERT PANEL (06/26/85-06/28/85)
2013-117	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marilyn Peguero-Fain freelance reporter	CRANIAL ORTHOSIS DEVICES - COMPLAINTS, FULL REPORTS
2013-118	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	XTANDI (ENZALUTAM DE, MDV3100) - AERS 1/1/10 TO PRESENT

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2013-119	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sajjan Aryal Accucaps Industries Limited	MSN LABORATORIES LTD, ANDHRA PRADESH, INDIA - EIR (03/5/12)
2013-120	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Orange Book archive DATAMONITOR HEALTHCARE CONSULTING	ORANGE BOOK - 2006
2013-121	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/COS/OES/ OC/COS/OES/ OM/OMP/DODM/	Rachel Johnson FOI Services, Inc.	THALIDOMIDE, THALOMID - COMMUNICATIONS, APPROVALS, RESTRICTIONS, ETC
2013-122	01/07/2013 02/05/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	MARY SCHWAGER WHDH-TV INC	D'ORO FOODS INC, MALDEN, MA; GATE GOURMET INC UNIT 231, EAST BOSTON, MA; DELTA AIR LINES INC, EAST BOSTON, MA, ETC - 483S
2013-123	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deb Hogerman UCB, Inc.	BLA 125160 S 080
2013-124	01/07/2013 02/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INTRADERMAL VACCINE LOT NUMBER UT4463AA - VAERS
2013-125	01/07/2013 03/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Walter Kyle Walter Kyle	IPV, EIPV - UNPUBLISHED DATA AVAILABLE FROM SANOFI PASTEUR SA AND INC
2013-126	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrea McCready McCready, Andrea	K030765, K844550
2013-127	01/07/2013 02/05/2013	OM/OMP/DODM/	Walter Kyle Walter Kyle	VRBPAC - TRANSCRIPTS (07/29/85, 7/30/85)
2013-128	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathon Doherty Milagro Community Care	XANAX - CLINICAL TRIALS, CORR

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2013-129	01/07/2013 02/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Schmidt COWEN AND COMPANY	BREAKTHROUGH CANDIDATES
2013-130	01/07/2013 02/05/2013	ORA/ ORA/	Doe J	INDIVIDUAL RECS
2013-131	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA BHATT HODGSON RUSS LLP	3M - LAVA ULTIMATE CAD/CAM RESTORATIVE K122569
2013-132	01/07/2013 04/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARTIN RUBENSTEIN HOWARD M FILE ATTY	INDIVIDUAL RECS - VAERS
2013-133	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BRIANNE RIDEOUT ASHCRAFT & GEREL LLP	CELLULAR TELEPHONE DVCS- SCIENTIFIC STUDIES, CORR, INVESTIGATIONS, ETC
2013-134	01/07/2013 02/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	J. DONALD HENSON, SR HENSON SR., J. DONALD	MEDTRONIC - INSULIN PUMP P980022 RECS
2013-135	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KYOCERA Medical Corporation KYOCERA Medical Corporation	K041940
2013-136	01/08/2013 02/06/2013	FDA/OC/OES/DFOI/	JOHN A. HOWARD-ALGARIN BAMUNDO ZWAL ET AL	LAPAROSCOPIC TOCAR INJURIES RPT - CERTIFIED COPY
2013-137	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Harris Biosim	NDA 008372; NDA 017861; NDA 010831 ETC
2013-138	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	ANDERSON, CARL.	LABPE.COM - SALE OF PEPTIDES, ANABOLIC STEROIDS 1/11 TO PRESENT
2013-139	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/	ANDERSON, CARL.	AJ GLOBAL LTD, DERL & EXTREME PEPTIDES.COM - SALE OF PEPTIDES, ANABOLIC STEROIDS 1/11 TO PRESENT

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		ORA/OCI/		
2013-140	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bill Orr Bill Orr	CHANTIX - AERS
2013-141	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K060866
2013-142	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Reed Celsus Laboratories, Inc.	SHENZHEN HEPALINK PHARMACEUTICAL CO LTD, GUANGDONG PROVINCE, CHINA - 483 , EIR (11/15/2008 - 01/07/2013)
2013-143	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K001368
2013-144	01/08/2013 02/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Glenn Irish Glenn Irish Consulting	SHIRE HGT - 483 (11/07/2011 - 01/07/2013)
2013-145	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BioCare Biocare Enterprise Limited	K002712
2013-146	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ismail Elchagea International Trading Pharmaceutical Lab	NEXAVAR TABLETS - IND, NDA
2013-147	01/08/2013 02/06/2013	CVM/OCD/ OC/COS/OES/ OC/COS/OES/ OM/OMP/DODM/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	ZILMAX (ZILPATEROL) APRVL, AER, WARNING LTRS
2013-148	01/08/2013 02/06/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	BRENDA M. GARTZ ELI LILLY & CO	OZBURN HESSEY LOGISTICS WAREHOUSE, KANSAS CITY, MO - EIR 12/11
2013-149	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	PATHEON BURLINGTON CENTURY OPERATIONS, BURLINGTON, CANADA - EIR 2/11
2013-150	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	PATHEON TORONTO REGION OPERATIONS, MISSISSAUGA, CANADA - EIR 2/11

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-151	01/08/2013 02/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LEAH GOMEZ THE HUMANE SOCIETY OF THE UNITED STATES	ENVIRONMENTAL ENHANCEMENT PLAN FOR NON HUMAN PRIMATES BY HSUS
2013-152	01/08/2013 02/06/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Herriot Tabuteau Axsome Therapeutics, Inc.	CALCITONIN HUMAN FOR INJECTION - ORPHAN DESIGNATION
2013-153	01/08/2013 02/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ya Ping Lee School of Pharmacy Curtin University	OMEPRAZOLE, ESOMEPRAZOLE, LANSOPRAZOLEM ETC - AERS
2013-154	01/08/2013 02/06/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG (12/31/2012 - 01/04/2013)
2013-155	01/08/2013 02/06/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Dan Reed Celsus Laboratories, Inc.	PHARMACIA HEPAR INC, FRANKLIN, OH - 483, EIR, CORR (01/01/2011 - 01/07/2013)
2013-156	01/08/2013 02/06/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	KRISTINA FRYE FRYE ELECTRONICS	FRYE ELECTRONICS, TIGARD, OR - EIR 6/22-7/3/12
2013-157	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K972527
2013-158	01/08/2013 02/06/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-	Richard P Dickey, MD, PhD Fertility Institute of New Orleans	IVF CLINICS - DISASTER RESPONSE INSPECTIONS (08/21/12-8/30/12)

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		DO/DAL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/		
2013-159	01/08/2013 02/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Doe J	LORAZEPAM; DIPHENHYDRAMINE; DOXEPIN; VALPROIC ACID SYRUP; MIRTAZAPINE - AER
2013-160	01/08/2013 02/06/2013	FDA/OGROP/ORARO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORT 20120103-1
2013-161	01/08/2013 02/06/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	MURIS DEMIROVIC FDA NEWS	MINDRAY DS USA INC, MAHWAY, NJ - 483 6/11/12 - 8/2/12
2013-162	01/08/2013 02/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK - HERPEX ZOSTER RECORDED IN THE MINI SENTINEL DATABASE AER
2013-163	01/08/2013 02/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	GAVIN ANDERSON AZAYA THERAPEUTICS INC	DOXIL NDA 50-718 - SUPPLEMENTAL NDA
2013-164	01/08/2013 02/06/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRUCE W. STECKLER STECKLER LAW LLP	AMGEN INC - EPOETIN ALFA (EPOGEN)
2013-165	01/08/2013 02/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	HENSON SR., J. DONALD	PMA P980022
2013-166	01/08/2013 02/06/2013	OC/OM/OMP/DDM/	SEAN CRANSHAW THE PEW CHARITABLE TRUSTS	DKT 1993N-0029, 1980N-0446, ETC.
2013-167	01/09/2013 02/07/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Aaron Diamant WSB-TV	GATE GOURMET, ATLANTA HARTSFIELD JACKSON INTERNATIONAL AIRPORT - EIR, WARNING LETTER, CORR, ETC (12/01/2012 - 01/07/2013)
2013-168	01/09/2013 02/07/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Dan Reed Celsus Laboratories, Inc.	SCIENTIFIC PROTEIN LABORATORIES LLC, WAUNAKEE, WI - 483, EIR (12/09/2009 - 01/07/2013)
2013-169	01/09/2013 02/07/2013	OC/OM/OMP/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2012-N-0378

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2013-170	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Reed Celsus Laboratories, Inc.	NANKING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL CO, JIANGSU - 483, EIR (09/01/2009 - 01/07/2013)
2013-171	01/09/2013 02/07/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Dan Reed Celsus Laboratories, Inc.	ORGANON API, INC, SIOUX CITY, IA - 483, EIR (02/01/2009 - 01/07/2013)
2013-172	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Reed Celsus Laboratories, Inc.	BIOBERICA, SA, BARCELONA, SPAIN - 483, EIR (03/15/2009 - 01/07/2013)
2013-173	01/09/2013 02/07/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Ann M. Carvalho McLarens Global Claim Services	SNYDER'S LANCE, CHARLOTTE, NC AND COLUMBUS, GA - INVESTIGATION RECS, REPORTS, INSPECTION RECS ETC (03/01/2012 - 01/07/2013)
2013-174	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K121598
2013-175	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Collie J. R. Collie Associates, Inc.	K102758
2013-176	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty Johnson Betty Johnson	K102727
2013-177	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty Johnson Betty Johnson	K121091
2013-178	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty Johnson Betty Johnson	K113479
2013-179	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	K110735
2013-180	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mick Fenton Immunodiagnostic Systems Ltd	K831178
2013-181	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY K STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	XANDI (ENZALUTAMIDE) - AERS 8/31/12 TO PRESENT
2013-182	01/09/2013	OM/OMP/DODM/	JANNA DEPORTER	DKT 1999P-2630

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	02/07/2013		CENTER FOR SCIENCE IN PUBLIC INTEREST	
2013-183	01/09/2013 03/15/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OF/CFSAN/OCD/EOS/	PATTI WELLER MARLER CLARK ATTYS	STATE GARDEN INC - ORGANIC SPINACH AND SPRING MIX BLEND E COLI OUTBREAK INVESTIGATION RECS, LAB RESULTS, CORR, ETC11/2/12
2013-184	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAIL C TRABISH ESQ BOORNAZIAN JENSEN & GARTHE PC	VALIDUS PHARMS - EQUETRO CORR, APRVL RECS, LBLG, ETC
2013-185	01/09/2013 02/07/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2012-8987
2013-186	01/09/2013 02/07/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER CONNER AMERICAN CLAIMS MANAGEMENT	BRIGHT REHAB SOLUTIONS INC, BAKERSFIELD, CA; GLENDALE, CA - IMPORTER REGISTRATION, EIRS, 483S, ETC 2009 TO PRESENT
2013-187	01/09/2013 02/07/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON BURLING LLP	COCA-COLA - FULL THROTTLE & NOS; DR PEPPER- VENOM; PEPSICO - AMP & ADRENALINE RUSH CAERS
2013-188	01/09/2013 02/07/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON BURLING LLP	TOTAL NUMBER OF PROVISIONAL AND NON-PROVISIONAL TOBACCO PROD SUBSTANTIAL EQUIVLENCE (SE) RPTS, MODIFIED RISK TOBACCO PRODS, ETC
2013-189	01/09/2013 02/07/2013	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	RANBAXY, OHM - BLOOMBERG NEWS, NEW YORK TIMES ATORVASTATIN REQUESTS
2013-190	01/09/2013 02/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MEMOS, CORR, EMAIL WHICH DISCUSS THE INCIDENCE OF HERPES ZOSTER DURING THE POST-MARKETING PERIOD IN INDIVIDUALS VACCINATED WITH ZOSTAVAX
2013-191	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heuston, Brian	ADVIL PM - AERS
2013-192	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heuston, Brian	TYLENOL PM - AERS

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2013-193	01/09/2013 02/07/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BRENDA M GARTZ ELI LILLY & CO	PROVIMI NORTH AMERICA, LEWISBURG, OH - EIRS 3/11, 10/11
2013-194	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	QILU PHARMACEUTICAL FACTORY, JINAN, CHINA - EIR 7/11
2013-195	01/09/2013 02/07/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	SANDOZ, WILSON, NC - EIR 6/11
2013-196	01/09/2013 02/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	LISA BURNS CHURCH & DWIGHT CO INC	SPD SWISS PRECISION DIAGNOSTICS GMBH - K112870
2013-197	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALBERTO ORTEGA UNIV OF FLORIDA WARRINGTON COLLEGE OF BUSINESS	ORANGE BOOK, NDC DIRECTORY 2001 TO 2011
2013-198	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	C RICHARD MARSHALL C RICHARD MARSHALL LAW OFCS	TRAMADOL - AERS
2013-199	01/09/2013 02/07/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	MP BIOMEDICALS LLC, SOLON, OH - EIRS, 488S, RECALLS 1/11 TO PRESENT
2013-200	01/09/2013 02/07/2013	ORA/ ORA/	INGRID S MARTIN COLLORA LLP	AMERIDOSE LLC - RAW MATERIAL, ENVIRONMENTAL SPL TEST RESULTS
2013-201	01/09/2013 02/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	CROSBY T-50417, COURTNEY	GRANUFLO, NATURLYT - BLACK BOX WARNING, RECALL RECS
2013-202	01/10/2013 02/08/2013	FDA/OF/CFSAN/OCDE/EOS/	Lena Gomez Keller and Heckman, LLP	FDA OPINION LETTER RE MILK PROTEIN CONCENTRATE

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2013-203	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	MAREK KUNECKI, LODZ, POLAND - 483 MOST RECENT
2013-204	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Oberlender Synthonics, Inc.	SINEMET, SINEMET CR - SBA
2013-205	01/10/2013 02/08/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Leslie Paul PERRIGO CO	ALTARIE PHARMACEUTICALS, AQUEBOGUE, NY - EIR, 483 (2/01/2010 - 01/08/2013)
2013-206	01/10/2013 02/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	AYA NAGANO KYOCERA Medical Corporation	K120370
2013-207	01/10/2013 02/08/2013	ORA/ ORA/	Loren Larkin LARKIN, LOREN	ST JUDE MEDICAL, SYLMAR, CA AND SAN JUAN, PR - RESPONSE TO 483 (11/02/2012 - 01/09/2013)
2013-208	01/10/2013 02/08/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan Zand, PharmD UpToDate a div of Wolters Kluwer Health	APIXABAN - SBA
2013-209	01/10/2013 02/08/2013	FDA/OF/CFSAN/OCD/EOS/	Judy Negley Valspar Corporation	FCN 635
2013-210	01/10/2013 02/08/2013	OM/OMP/DODM/	ronald piana Ronald Piana	IMMUNOLOGY DEVICES ADVISORY PANEL MEETING - TRANSCRIPT (12/09/1985)
2013-211	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	jack rubinstein UNIVERSITY OF CINCINNATI	PROBENECID - APPROVAL RECS
2013-212	01/10/2013 02/08/2013	FDA/OF/CFSAN/OCD/EOS/	Ryan Simon CANTOX Health Sciences International	FRUIT/VEGETABLE JUICE COLORING - OPINION LETTERS AND CORR
2013-213	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketan Parekh Parekh, Ketan	IND 18004, NDA 019839

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-214	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 200644 - EFFECTIVE APPROVAL LETTER
2013-215	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marie-Hlne Dancause pharmacist, Hôtel-Dieu de Lévis	VYVANSE - AERS
2013-216	01/10/2013 02/08/2013	CVM/OCD/ OM/OMP/DODM/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	SUITABILITY PETITION 09P-0306/CPI
2013-217	01/10/2013 02/08/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	RICHARD C. BADEAUX DEGAN BLANCHARD EL AL	CREATIVE COMPOUNDS LLC, SCOTT CITY, MO - EIR 1/15/10 METAL ANTIMONY IN STEVIA LEAF EXTRACT
2013-218	01/10/2013 02/08/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	TEDD KESSLER LAW OFFICE OF TED KESSLER PC	STRYKER TRIDENT - CEMENTLESS CUPS, POLYETHYLENE SHELLS; SECUR FIT MAX STRYKER STEMS CMLPNTS, WARNING LTR, MDRS 2005 TO PRESENT
2013-219	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEUSTON 240731, BRIAN	AMITRIPTYLINE - AER
2013-220	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEUSTON 240731, BRIAN	ELAVIL - AER
2013-221	01/10/2013 02/08/2013	FDA/OC/OES/DFOI/	ANDREWS D17561, JOHN	MORTON GROVE PHAMACEUTICAL - SELENIUM SULFIDE LOTION; PERRIGO - SELENIUM SULFIDE TOPICAL SUSPENSION

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2013-222	01/10/2013 02/08/2013	CVM/OCD/ FDA OM/OMP/DODM/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	SUITABILITY PETITION 2-P-0945-0001
2013-223	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ketan Parekh Parekh, Ketan	MIRENA - IND, NDA
2013-224	01/10/2013 02/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	INFLUENZA VACCINE - VAERS
2013-225	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kim Capone Porzio Life Sciences	SERAX - REGULATORY LETTER ISSUED BY THE DIVISION OF ADVERTISING, BUREAU OF DRUGS (01/01/1975 - 01/31/1975)
2013-226	01/10/2013 02/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	DEEP TMS BY BRAINSWAY - 510K
2013-227	01/10/2013 02/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Edward McPike Stifel Nicolaus & Co	NUSKIN - APPLICATION FOR CLEARANCE OF A FACIAL SPA UNIT
2013-228	01/10/2013 02/08/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/ ORA/OCI/ ORA/OCI/	PAMELA BROOKS FIRST RECORDS RETRIEVAL	REFUSE OF SINGLE USE ENDOCAVITY NEEDLE GUIDES RECS 1/10 TO PRESENT
2013-229	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/ FDA/OC/OES/DFOI/ ORA/ ORA/	PAUL W. SHAW K&L GATES	NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA - INVESTIGATION RECS, LAB ANALYSES, TEST RESULTS, ETC 9/12 TO 10/12
2013-230	01/10/2013 02/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	ANDA 40-445 APRVL

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2013-231	01/10/2013 02/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A. LUKE SMITH FARUQI & FARUQI LLP	ANDA 40-445 CROSS DISP RVW SUMMARY, SUMMARY RVW
2013-232	01/10/2013 02/08/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 12/24-28/12
2013-233	01/11/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Tara J. Myslinski O'Connor, Carnathan & Mack, LLC	HEALTHPOINT - CORR RE HP802, ICX-SKN, OASIS, ETC
2013-234	01/11/2013 02/11/2013	OM/OMP/DODM/	Sue Corbett THE RESEARCH INVESTMENT, INC.	SPECIAL REPORT TO FDA PUBLIC MEETING ON RE-EVALUATION OF RITODRINE LABELING (1992)
2013-235	01/11/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Don Hammond Raymond Paul Johnson, A Law Corporation	EMBASSY SUITES, LA JOLLA, CA - PERMITS, COMPLAINTS, INSPECTION RECORDS ETC (05/22/2012 - 01/09/2013)
2013-236	01/11/2013 02/11/2013	FDA/OF/CFSAN/OCD/EOS/	Kayla Conroy Kayla Conroy	FOOD ADDITIVE PETITIONS FOR ARTIFICIAL SWEETENERS ETC
2013-237	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joel Hoekstra Fresenius Kabi USA	NDA019952, NDA019953, NDA018609 ETC - SBA
2013-238	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Sarah Geisert GENERAL MILLS	GENERAL MILLS, WEST CHICAGO, IL - EIR 06/10; GENERAL MILLS, LODI, CA 08/10; GENERAL MILLS, BELVIDERE, IL - EIR 10/11
2013-239	01/11/2013 02/11/2013	ORA/OCI/ ORA/OCI/	Christpher Weaver THE WALL STREET JOURNAL	MEDIPLAN HEALTH CONSULTING, RXNORTH.COM - INVESTIGATION RECS

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2013-240	01/11/2013	OC/OOPD/	HeeSun Lee	ANATIBANT - ORPHAN PRODUCT DESIGNATION
	02/11/2013	FDA/OMPT/OSMP/OOPD/	Aclairo Pharmaceutical Development Group	
2013-241	01/11/2013	FDA/OC/OES/DFOI/	Christopher Weaver	MEDICAL DEVICE INOPERABILITY, SECURITY, CONNECTIVITY - FOIA REQUESTS AND STATUS (01/01/2011 - 01/10/2013)
	02/11/2013		THE WALL STREET JOURNAL	
2013-242	01/11/2013	FDA/OC/OES/DFOI/	Christopher Weaver	COUNTERFEIT MEDICINES, MISBRANDED MEDICINES, UNAPPROVED MEDICINES - FOIA REQUESTS AND STATUS (01/01/2011 - 01/10/2013)
	02/11/2013		THE WALL STREET JOURNAL	
2013-243	01/11/2013	FDA/OC/OES/DFOI/	Christopher Weaver	MASIMO CORP, COVIDIEN PLC, MINDRAY ETC - FOIA REQUESTS
	02/11/2013		THE WALL STREET JOURNAL	
2013-244	01/11/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Leslie Paul	INTERNATIONAL VITAMIN CORP, FREEHOLD, NJ - 483, EIR (11/21/2011)
	02/11/2013		PERRIGO COMPANY	
2013-245	01/11/2013	FDA/OMPT/CDER/ORP/DIDP/	Stephen From	NDA 022212 (DUREZOL) - MEDICAL REVIEW
	02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eyegate Parmaceuticals, Inc.	
2013-246	01/11/2013	ORA/OCI/	Christopher Weaver	INVESTIGATION RECS
	02/11/2013	ORA/OCI/	THE WALL STREET JOURNAL	
2013-247	01/11/2013	FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson	NDA 203752
	02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2013-248	01/11/2013	FDA/OF/CFSAN/OCD/EOS/	Alex Morrell	REGULATION OF DIETARY AND FITNESS SUPPLEMENTS - CAERS, EMAIL, MEMOS, ETC
	02/11/2013	OC/COS/OES/ OC/COS/OES/	Columbia School of Journalism	
2013-249	01/11/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Michael C. Cotugno	ANALYTICAL RESEARCH LABORATORIES, OKLAHOMA CITY, OK - 483 MOST RECENT(08/01/2012 - 01/10/2013)
	02/11/2013		Cotugno, Michael C	
2013-250	01/11/2013	OC/OOPD/	HeeSun Lee	DEXANABINOL - ORPHAN DESIGNATION
	02/11/2013	FDA/OMPT/OSMP/OOPD/	Aclairo Pharmaceutical Development Group	
2013-251	01/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Thorpe	K993438, K011110, K042037 ETC
	02/11/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Thorpe, Joseph	
2013-252	01/11/2013	FDA/OMPT/CDER/ORP/DIDP/	GORDON JOHNSTON	HIKMA FARM - DILTIAZEM HCL ANDA 202-651: MYLAN LLC

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	02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GORDON JOHNSTON REGULATORY CONSULTANTS LLC	- TOPOTECAN HCL ANDA 201-166; ONCO THERAPIES LTD - CYTARABINE ANDA 201-784, ETC TENTATIVE APRVL LTR
2013-253	01/11/2013 02/11/2013	ORA/ORM/ ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 12/1- 31/12
2013-254	01/11/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	JOHNATHAN RICKMAN FDA NEWS	PRECISION INTERCONNECT LLC (CONNECTIVITY MEDICAL), WILSONVILLE, OR; ADVANCED RENAL TECHNOLOGIES INC, BELLEVUE, WA - 483S 11/1-30/12
2013-255	01/11/2013 02/11/2013	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	INTEGRA NEUROSCIENCES PR INC, ANASCO, PR - 483S 11/1-30/12
2013-256	01/11/2013 02/11/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	JOHNATHAN RICKMAN FDA NEWS	BECTON DICKINSON AND CO, WILSON, NC; BEAUMONT PRODUCTS INC, KENNESAW, GA; DSM PHARMACEUTICALS INC, GREENVILLE, NC, ETC - 483S 11/1-30/12
2013-257	01/11/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	JOHNATHAN RICKMAN FDA NEWS	ALEXZA PHARMACEUTICALS INC, MOUNTAIN VIEW, CA; NEVRO CORP, MENLO PARK, CA; CLAREBLEND INC, RENO, NV, ETC - 483S 11/1-30/12
2013-258	01/11/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHNATHAN RICKMAN FDANEWS	I HEALTH INC, WINDSOR, CT; ARTHROSURFACE INC, FRANKLIN, MA; ANIKA THERAPEUTICS INC, BEDFORD, MA - 483 11/12
2013-259	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	PHOTOMEDEX INC, MONTGOMERYVILLE, PA; BIO-PHARM INC, LEVITTOWN, PA - 483S 11/1-30/12
2013-260	01/11/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JOHNATHAN RICKMAN FDA NEWS	FOUGERA PHARMACEUTICALS INC, HICKSVILLE, NY; NOVA HEALTH SYSTEMS INC, UTICA, NY; QUANTUM MEDICAL IMAGING LLC, RONKONKOMA, NY, ETC - 483S 11/1-30/12
2013-261	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	CARMA LABORATORIES INC, FRANKLIN, WI; MODERN PRODUCTS INC, MEQUON, WI; NONIN MEDICAL INC, PLYMOUTH, MN - 483 11/12
2013-262	01/11/2013 02/11/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	JOHNATHAN RICKMAN FDANEWS	VILEX IN TENNESSEE INC, MCMINNVILLE, TN; HEALTH SCIENCE PRODUCTS INC, HUEYTOWN, AL; AIONEX INC, GOODLETTSVILLE, TN, ETC - 483S 11/1-30/12
2013-263	01/11/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	WATSON LABORATORIES INC, CORONA, CA; EVOFEM INC, SAN DIEGO, CA; RA MEDICAL SYS INC, CARLSBAD, CA - 483 11/12
2013-264	01/11/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	APTUIT LLC, HARRISONVILLE, MO - 483 11/12
2013-265	01/11/2013 02/11/2013	ORA/ ORA/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	ORION CORP, ESPOO, FINLAND; AARTI DRUGS LTD. MAHARASHTRA STATE, INDIA - 483 11/12

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2013-266	01/11/2013 02/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JHONATHAN RICKMAN FDA NEWS	OMRIX BIOPHARMACEUTICALS LTD, KIRYAT-ONO, ISRAEL; VETTER PHARMA FERTIGUNG GMBH & CO KG, RAVENSBURG, GERMANY; DOMINION BIOLOGICALS LTD, DARTMOUTH, CANADA - 483 11/12
2013-267	01/11/2013 02/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	TABERNA PRO MEDICUM, LUENBURG, GERMANY; FISIOLINE SRL, VERDUNO, ITALY; LINET SPOL SRO, SLANY, CZECH REPUBLIC - 483 11/12
2013-268	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICAL INNOVATIONS INC, NEWARK, NJ; VECTRACOR INC, TOTOWA, NJ; BIPORE MEDICAL DEVICES INC, NORTHVALE, NJ, ETC - 483S 11/1-30/12
2013-269	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 12/1- 31/12
2013-270	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	JIANGXI TIANXIN PHARMACEUTICAL CO LTD, LEPING, CHINA; CHIA GI LTD, CHIOS, GREECE; GRISI HNOS SA DE CV, MEXICO - 483 11/12
2013-271	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	KATH KHEMICALS LLC, STERLING HEIGHTS, MI; STRYKER INSTRUMENTS, PORTAGE, MI; DEPUY ORTHOPAEDICS INC, WARSAW, IN - 483 11/12
2013-272	01/11/2013 02/11/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	DERMAZONE SOLUTIONS INC; SAINT PETERSBURG, FL; AIG TECHNOLOGIES INC, DEERFIELD BEACH, FL; VALJEAN CORP, INDIAN HARBOUR BEACH, FL - 483 11/12
2013-273	01/11/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	NEXGEN PHARMA INC, COLORADO SPRINGS, CO; CARDINAL HEALTH 414 LLC; DENVER, CO; PARKWAY PRODUCTS INC, LOVELAND, CO - 483 11/12
2013-274	01/11/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	RX AIR INDUSTRIES LLC, FARMERS BRANCH, TX; AMERICAN AESTHETICS MEDICAL SUPPLY INC, DALLAS, TX; OHM PHARMACEUTICAL INC 414 INC, DALLAS, TX - 483 11/12
2013-275	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	FOREST PHARMACEUTICALS INC, CINCINNATI, OH; HUNT BROTHERS PRODUCTS, ZANESVILLE, OH; SYNAPSE BIOMEDICAL INC, OBERLIN, OH - 483 11/12
2013-276	01/11/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	AMICUCCI, PHYLLIS	DR SAUD A SADIQ, MULTIPLE SCLEROSIS RESEARCH CENTER OF NEW YORK, NEW YORK, NY - CESSATION OF

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		FDA/OMPT/CBER/OCOD/DDOM/ALFB/		THE STEM CELL TRIAL RECS 2012
2013-277	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	DANIELS SHARPSMART INC, CHICAGO, IL; CORPAK MEDSYSTEMS, BUFFALO GROVE, IL - 483 11/12
2013-278	01/11/2013 02/11/2013	ORA/ ORA/	MARIA MUNOZ SEADCO USA CORP	FROZEN PASTEURIZED EXTRA JUMBO MARISSIMO U-250, EXTRA JUMBO SEADCO U-130 ENTRY #E4P-0022287-7 - LAB RESULTS
2013-279	01/11/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	CUSTOM HEALTHCARE SYSTEMS INC, RICHMOND, VA; FUTREX INC, HAGERSTOWN, MD; UPM PHARMS, BALTIMORE, MD - 483 11/12
2013-280	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ FDA/OC/OES/DFOI/ ORA/ ORA/ OC/OL/	ALAN M FELDMAN FELDMAN SHEPHERD ET AL	ALAUNUS PHARMACEUTICAL LLC - RECALLS, CMLPTS, TRANS, ETC 1/95 TO PRESENT
2013-281	01/11/2013 02/11/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT FDA-2012-P-0904
2013-282	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 12/24-28/12
2013-283	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 12/24-28/12
2013-284	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ FDA/OC/OES/DFOI/	ALAN M FELMAN FELDMAN SHEPHERD ET AL	NEW ENGLAND COMPUNDING PHARMACY INC - RECALLS, CMLPTS, VIOLATION RPTS, ETC 1/95 TO PRESENT

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		ORA/ ORA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OL/		
2013-285	01/11/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ FDA/OC/OES/DFOI/ ORA/ ORA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OL/	ALAN M FELDMAN FELDMAN SHEPHERD ET AL	AMERIDOSE LLC - RECALLS, CMPLNTS, VIOLATION RPTS, ETC 1/95 TO PRESENT
2013-286	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 12/24-28/12
2013-287	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 12/24-28/12
2013-288	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 12/24-28/12
2013-289	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 12/24-28/12
2013-290	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 12/24-28/12
2013-291	01/11/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND	CLOSED FOI REQUESTS 12/24-28/12

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	02/11/2013		FDA WEBVIEW/FERDIC INC	
2013-292	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 12/24-28/12
2013-293	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/24-28/12
2013-294	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	DAILY LOG 12/17-21/12
2013-295	01/11/2013 02/11/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	DAILY LOG 12/24-28/12
2013-296	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA21435
2013-297	01/13/2013 02/11/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	C Hartill RTI Biologics, Inc	MUSCULOSKELETAL TRANSPLANT FOUNDATION, EDISON, NJ - 483 (09/24/2012 - 12/31/2012)
2013-298	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Chelsea A. Loughran Wolf Greenfield & Sacks, P.C.	ANTIVIPMYN, ANTIVENIN, ANTIVENOM - FORM 1571, FORM 1572, ETC
2013-299	01/13/2013 02/11/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	TISSUE PLASMINOGEN ACTIVATOR - ORPHAN PRODUCT DESIGNATION
2013-300	01/13/2013 02/11/2013	ORA/ORM/ ORA/ORM/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	GLP INSPECTIONS, BIOEQUIVALENCE LABORATORIES, ANALYTICAL LABORATORIES - LIST OF INSPECTIONS 2011-2012
2013-301	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Richard W. Gonnello Faruqi & Faruqi, LLP	BIOSANTE PHARMACEUTICALS LIBIGEL DRUG DEVELOPMENT PROGRAM - SPECIAL PROTOCOL ASSESSMENT, PHASE II CLINICAL TRIAL DATA, PHASE III EFFICACY CLINICAL TRIALS ETC
2013-302	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103780/5121

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-303	01/13/2013 02/11/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	NIMODIPINE - ORPHAN DRUG DESIGNATION
2013-304	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sina Carlson Carlson, Sina	BINOSTO - BIOEQUIVALENCE STUDIES
2013-305	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ralph Harris SAMFORD UNIVERSITY	TACROLIMUS, CYCLOSPORIN - AERS
2013-306	01/13/2013 02/11/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	CYCLOSPORINE - ORPHAN DRUG DESIGNATION
2013-307	01/13/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Leslie Paul PERRIGO COMPANY	TWINLAB CORPORATION, AMERICAN FORK, UT - 483, EIR (11/01/2011 - 12/20/2011)
2013-308	01/13/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Leslie Paul PERRIGO COMPANY	NUTRO LABORATORIES, S PLAINFIELD, NJ - EIR (01/15/2012 - 02/28/2012)
2013-309	01/13/2013 02/11/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Leslie Paul PERRIGO COMPANY	NBTY BOCA RATON, FL - 483, EIR (09/15/2010 - 10/30/2010)
2013-310	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Mark Pregonzer Ronald Reagan UCLA Medical Center	OCUCOAT - APPROVAL ORDER, SUMMERY OF SAFETY AND EFFECTIVENESS
2013-311	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125104/33 - SUPPLEMENTAL APPROVAL INFORMATION
2013-312	01/13/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Leslie Paul PERRIGO COMPANY	PHARMAVITE LLC, VALENCIA, CA - EIR (11/15/2010 - 01/01/2011)
2013-313	01/13/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Leslie Paul PERRIGO CO	NBTY, BOHEMIA, NY - 483, EIR (02/01/2012 - 03/10/2012)

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2013-314	01/13/2013 02/11/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Leslie Paul PERRIGO COMPANY	CAPSULEWORKS, BAYPORT, NY - EIR (02/10/2009 - 03/25/2009)
2013-315	01/13/2013 02/11/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	PROGESTERONE - ORPHAN DRUG DESIGNATION
2013-316	01/13/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Leslie Paul PERRIGO COMPANY	NBTY MANUFACTURING LLC, ANAHEIM, CA - EIR (06/01/2011 - 07/31/2011)
2013-317	01/13/2013 02/11/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Stephen From Eyegate Pharmaceuticals, Inc.	DUREZOL - ORPHAN DRUG DESIGNATION
2013-318	01/13/2013 02/11/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	HeeSun Lee Aclairo Pharmaceutical Development Group	APOMORPHINE HYDROCHLORIDE - ORPHAN DRUG DESIGNATION
2013-319	01/13/2013 02/11/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Leslie Paul PERRIGO COMPANY	NBTY LLC, CARSON, CA - EIR (11/15/2010 - 01/05/2011)
2013-320	01/13/2013 02/11/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Leslie Paul PERRIGO COMPANY	NBTY, INC, CARBONDALE, IL - EIR (10/10/2011 - 11/10/2011)
2013-321	01/13/2013 02/11/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ ORA/OCI/ ORA/OCI/	Gary Wittenberg Baranov & Wittenberg, LLP	FLANDERS PHARMACY, CLACKAMAS, OR; PACIFIC FRONTIER MEDICAL, REDWOOD CITY, CA - TEST RESULTS
2013-322	01/13/2013 02/11/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Michael Priest Self	CARGILL, INC, DES MOINES, IA - REPORT ABOUT FOOD SAFETY CONCERNS
2013-323	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Richard W. Gonnello FARUQI & FARUQI LLP	CHELSEA THERAPEUTICS INTERNATIONAL - ORPHAN DRUG DESIGNATION, SPECIAL PROTOCOL ASSESSMENT, FAST TRACK STATUS, ETC
2013-324	01/13/2013 02/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ZOLPIDEM - CLINICAL TRIAL DATA, DRIVING SIMULATION STUDIES

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-325	01/13/2013 02/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	ZOLPIDEM - AERS
2013-326	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Doe J	NESTLE BENEALORIE NUTRITIONAL SUPPLEMENT - MANUFACTURING PROCESS
2013-327	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASSULO MD ASCEND CAPITAL LLC	NUJEDXTA (DEXTROMETHORPHAN HYDROBROMIDE & QUINIDINE SULFATE) CAPS - AERS 1/10 TO PRESENT
2013-328	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	JAKAFI (RUXOLITINIB) - AERS 1/10 TO PRESENT
2013-329	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	PONATINIB - AERS 1/10 TO PRESENT
2013-330	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	ENZALUTAMIDE - AERS 1/10 TO PRESENT
2013-331	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASULO ASCEND CAPITAL LLC	QSYMIA (PHENTERMINE & TOPIRAMETE ER) CAPS - AERS 1/10 TO PRESENT
2013-332	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	ABIRATERONE - AERS 1/10 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-333	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE CARESTREAM HEALTH INC	RIVERAIN MEDICAL GROUP - SOFTVEIW SYS K092363
2013-334	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRANK E EPPERSON DDS	HYPODERMIC SYRINGE - GRANDFATHER DETERMINATION DISPOSABLE CARPULE
2013-335	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JUSTIN LOVELACE TELEFLEX MEDICAL	PALL MEDICAL - PALL UTIPOR ANESTHESIA BREATHING CIRCUIT SYS K013093
2013-336	01/14/2013 02/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/	WILLIAM SARRAILLE SIDLEY AUSTIN LLP	ST JUDE - RESP TO 483, SUBMISIONS 7/1/12, 10/2/12
2013-337	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JASON MAHON PREMIER ORGANICS	PREMIER ORGANICS - NOTES, SUMMARIES, WARNINGS LTRS, ETC 1/07 TO 11/1/12
2013-338	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEROLA, ERIC	KURUME UNIVERSITY, KURUME, FUKUOKA PREFECTURE, JAPAN - REC 1988
2013-339	01/14/2013 02/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMBIEN - AERS
2013-340	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	MARLYN NUTRACEUTICALS INC - IMMUNE SYSTEM SUPPORT LEMON LIME TABS RECALL FDA SITE VISIT RECS 1988
2013-341	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	MARLYN NUTRACEUTICALS INC - IMMUNE SYSTEM SUPPORT ORANGE TABS RECALL RECS 8/17/10
2013-342	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	MARLYN NUTRACEUTICALS INC - AIR SHIELD PINK GRAPEFRUIT TABS RECALL RECS 8/17/10
2013-343	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	NBTY ACQUISTION LLC (LEINER HEALTH PRODS INC) - AIR SHIELD ORANGE TABS RECALL RECS 8/17/10; MARLYN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-344	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN	NBTY ACQUISTION LLC (LEINER HEALTH PRODS INC) - AIRHEALTH ORANGE TABS, AIR PROTECTOR ORANGE

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		DO/NYK-DCB/	LLP	TABS, AIR SHIELD ORANGE TABS, ETC RECALL RECS 8/17/10; MARYLN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-345	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	STACY LL CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	NBTY ACQUISITION LLC (LEINER HEALTH PRODS INC) - WALBORN LEMON LIME STICK PACK, AIRHEALTH LEMON LIME STICK PACK RECALL RECS 8/17/10;; MARLYN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-346	01/14/2013 02/12/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	STACY L CESLOWITZ SCHOEMAN UPDIKE & KAUFMAN LLP	NBTY ACQUISITION LLC (LEINER HEALTH PROD INC) - AIRHEALTH LEMON-LIME TABS, AIR PROTECTOR LEMON-LIME TABS, AIR SHIELD LEMON-LIME TABS RECALL, ETC RECS; MARLYN NUTRACEUTICALS INC - AFOREMENTIONED TABS COMM
2013-347	01/14/2013 02/12/2013	ORA/ ORA/	Doe J	CMPLNT
2013-348	01/14/2013 02/12/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	PAUL B CALLAHAN CHARLES RIVER LABS	NOVARTIS VACCINES & DIAGNOSTICS INC, EMERYVILLE, CA - 483S 7/7-15/10
2013-349	01/14/2013 02/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	PAUL B CALLAHAN CHARLES RIVER LABS	GLAXOSMITHKLINE BIOLOGIS, DRSDEN, GERMANY - 483S 6/14-22/11
2013-350	01/14/2013 02/12/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	PATRICIA SABATINI PITTSBURGH POST-GAZETTE	MYLAN INC - WARNING LTR RECS 11/9/12, 10/13/11
2013-351	01/14/2013 02/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	REMERON, WELLBUTRIN, GEODON - MED WATCH RPT
2013-352	01/14/2013 02/12/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	SAMANTHA MYERS ROANOKE TRADE SERVICES INC	SBL GLOBAL INC - ENTRY NUMBER WUG-01511467, WUG-01504843 NOTICES OF ACTION, COMMERCIAL INVOICES, BILLS OF LADING, ETC
2013-353	01/15/2013 02/13/2013	FDA/OC/OES/DFOI/	David Elder Parexel International	FOIA REQUEST LOG (07/01/2011 - 01/14/2013)
2013-354	01/15/2013 02/13/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Kristan Phillips MacroGenics	LONZA, PORTSMOUTH, NH - 483, EIR (01/01/2010 - 12/31/2010)
2013-355	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	ISR 6786292, 6806987, 6810329, ETC

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2013-356	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alison Sathe Ellman International	K040563
2013-357	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia Wojtaszek BRISTOL-MYERS SQUIBB	BLA 103705/5332
2013-358	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg, Esq. Law Firm of Eric Weinberg	PRADAXA - SUBMISSIONS, CORR
2013-359	01/15/2013 02/13/2013	FDA/OMPT/CTP/OD/	John Shoemaker Visium	ASSESSMENT OF THE IMPACT OF MENTHOLATED CIGARETTES ON SMOKING INITIATION, DEPENDENCE, AND CESSATION
2013-360	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/	Kevin S. Fries COSMETIC INGREDIENT REVIEW	VOLUNTARY COSMETIC REGISTRATION PROGRAM UPDATE (01/14/2012 - 01/14/2013)
2013-361	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne Ellipse Technologies, Inc.	K971783
2013-362	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/	Alan Rappeport FINANCIAL TIMES	HERBALIFE PRODUCTS - AERS
2013-363	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/COS/OES/ OC/COS/OES/ ORA/ ORA/	Thomas M. Burton THE WALL STREET JOURNAL	FDA CHINA AND INDIA OFFICES - CORR RE INSPECTIONS, SAFETY, AND COMPLIANCE OF DRUG OR API FACILITIES IN CHINA AND INDIA
2013-364	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	KYPER, CHARLES H	MED-KHAN (USA) INC - LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE K083455
2013-365	01/15/2013 02/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	GABAPENTIN, NEURONTIN 300MG - AERS
2013-366	01/15/2013	FDA/OF/CFSAN/OCD/EOS/	RAYMOND M DAVID PHD	D & C RED NO 9 ENTRY #237 IN CL NO 15585 - TOXICITY

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	02/13/2013		BASF CORP	STUDY
2013-367	01/15/2013 02/13/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	DR PHOEBE MOUNTS ESQ MORGAN LEWIS & BOCKIUS LLP	MUSCULOSKELETAL TRANSPLANT FOUNDATION - 483 12/12
2013-368	01/15/2013 02/13/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	CATERINA GULYAS G&W LABORATORIES INC	BIO-PHARM INC, LEVITTOWN, PA - EIRS, 483S, CO RESP LAST 6 MONTHS
2013-369	01/15/2013 02/13/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	CATERINA GULYAS G&W LABORATORIES INC	COUNTY LINE PHARMACEUTICALS LLC, BROOKFIELD, WI - EIRS, 483S, CO RESP LAST 6 MONTHS
2013-370	01/15/2013 02/13/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANDREA SESSIONS ESQ FREDERICK W SMITH JR LAW OFCS	ABBOTT LABS, ABBOTT DIABETES CARE - GLUCOSE TEST STRIP RECALL 12/22/10, Cmplnts, CORR, ETC
2013-371	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	KELLI DUNLAP KERCSMAR & FELTUS PLLC	HALODROL LIQUIGELS - RECAL RECS
2013-372	01/15/2013 02/13/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	MICHAEL J WINER ESQ MICHAEL J WINER LAW OFC	INDIVIDUAL RECS
2013-373	01/15/2013 04/11/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	MANUEL A MOLINA FREEHILL HOGAN & MAHARR LLP	FROZEN SHRIMP ENTRY #MWCU6099637 - CORR, RPTS, TESTING, ETC
2013-374	01/15/2013 02/13/2013	FDA/OC/OES/DFOI/	A LUKE SMITH FARUQI & FARUQI LLP	ANDA 40-445 - APRVL RECS
2013-375	01/15/2013 02/13/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	GISSENDANNER, ROBIN	CMPLNT #120110
2013-376	01/15/2013	FDA/OF/CFSAN/OCD/EOS/	JENESSA G B COCCARO	GASPARI NUTRITION INC - NOVEDX XT INVESTIGATION,

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	02/13/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	KERCSMAR & FELTUS PLLC	RECALL RECS, TRANS, ETC
2013-377	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - M-ONE-T RPTS, NOTICES, MINS, ETC
2013-378	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - ORASTA E RPTS, TRANS, NOTICES, ETC
2013-379	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JENESSA G B COCCARO KERCSMAR & FELTUS PLLC	GASPARI NUTRITION INC - OXAVAR RPTS, NOTICES, TRANS, ETC
2013-380	01/15/2013	FDA/OF/CFSAN/OCD/EOS/	JENESSA G B COCCARO	GASPARI NUTRITION INC - ORASTAN A RPTS, TRANS,

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	02/13/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KERCSMAR & FELTUS PLLC	NOTICES, ETC
2013-381	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159461
2013-382	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159486
2013-383	01/15/2013 02/13/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 159218, 160158
2013-384	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/	MICHAEL R SNEBERGER ESQ HBI INTERNATIONAL	HBI INTERNATIONAL - 905J RPTS SE0001698, SE0002348, SE0002350, ETC
2013-385	01/15/2013 02/13/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2012-8911
2013-386	01/15/2013 02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K120306
2013-387	01/16/2013 02/14/2013	OC/OM/OMP/DDM/	JEFF GERTH PROPUBLICA	DKT 1977N-0094
2013-388	01/16/2013 02/14/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Trevor C. Sanders AARON J. PRISBREY, P.C.	CODMAN DURAL GRAFT IMPLANT - MEMOS, REPORTS, STUDIES, ETC
2013-389	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123194
2013-390	01/16/2013 02/14/2013	ORA/ORM/ ORA/ORM/	Lee Ann Liss AbbVie	BIORESEARCH MONITORING - LIST OF DOMESTIC AND INTERNATIONAL INSPECTIONS (01/02/2001 - 12/31/2012)
2013-391	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Conlin N/A	K102342, K120563
2013-392	01/16/2013 02/14/2013	FDA/OF/CFSAN/OCD/EOS/	Kathy Lee General Mills, Inc.	FOOD GMP MODERNIZATION WORKING GROUP: SUMMARY OF FOOD RECALLS; ANALYSIS OF FOOD RECALLS INITIATED IN 2008-2009 BY AN FDA CGMP WORKING GROUP

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2013-393	01/16/2013 02/14/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	PARAXEL, LOWELL, MA - EIR, 483 (01/01/09 TO PRESENT)
2013-394	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nancy Gunderson Veritox	FDA GUIDELINES FOR REPRODUCTION STUDIES FOR SAFETY EVALUATION OF DRUGS FOR HUMAN USE
2013-395	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	William Fisher DJO, LLC	PMA 910066
2013-396	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lourdes Coba Beckman Coulter, Inc.	K112605
2013-397	01/16/2013 02/14/2013	OM/OMP/DODM/	Doreen Frank ENVISAGE CONSULTING LLC	DKT 76N-052T
2013-398	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hassan Ahmad International Trading Pharmaceutical Lab	LEUCOVORIN - ANDA
2013-399	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	OHAN ARAKELIAN COBEG WORLDWIDE, LLC	K871072, K871073, K871070 ETC
2013-400	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	TETRA GENX ANALYTICAL LABORATORY, ST LAURENT QUEBEC- EIR 4/12
2013-401	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	SMITH KLINE BEECHAM, WORTHING WEST SUXXES, UK - EIR 3/11
2013-402	01/16/2013 02/14/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	BRENDA M. GARTZ ELI LILLY & CO	SHEPPARD WOOD DISTRIBUTORS INC, NAMPE, ID - EIR 12/11
2013-403	01/16/2013 02/14/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	BURGESS, BERNIE	EXHIBITS FOR 2012-4657
2013-404	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ward Komers Golden West Biologicals, Inc.	K110641
2013-405	01/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ward Komers	K113177

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	02/14/2013		Golden West Biologicals, Inc.	
2013-406	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jason Walton Fogless International AB	K962714, K043160, K945407
2013-407	01/16/2013 02/14/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (01/07/2013 - 01/11/2013)
2013-408	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Audrey Spolarich audrey Spolarich	LEVAQUIN - AERS
2013-409	01/16/2013 02/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Sarah A. Ferrill SALVI SCHOSTOK & PRITCHARD PC	INDIVIDUAL RECS
2013-410	01/16/2013 02/14/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Tony Taylor Aesculap, Inc.	D-TARGET, QUINCY MA; D-TARGET, SWITZERLAND - 483, REPORTS
2013-411	01/16/2013 02/14/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SAMUEL F. COLIN MD FIRST MANHATTAN CO	LUITPOLD PHARMACEUTICALS INC - 483 2/9/11 TO 3/15/11
2013-412	01/16/2013 02/14/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ROBERT M. GOLDMAN CL King & Associates	HILL ROM INC, BATESVILLE, IN - 483 12/12 TO PRESENT
2013-413	01/16/2013 02/14/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	BETSY REDDINGTON LIGHT AGE INC	FEI 2246844
2013-414	01/16/2013 02/14/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	A. LUKE SMITH FARUQI & FARUQI LLP	OHM LABS, NJ - 483 2008 TO 2009
2013-415	01/16/2013 02/15/2013	OC/COS/OES/ OC/COS/OES/	JIM MORRIS CENTER FOR PUBLIC INTEGRITY	CORR BETWEEN AMERICAN CHEMISTRY COUNCIL & FDA 1/09 TO PRESENT
2013-416	01/16/2013 02/14/2013	FDA/OC/OES/DFOI/	DONALD F. SEGAL ALSTON & BIRD LLP	FOOD ADDITIVE PETITION FOIA SUBMITTED BY GRUMA CORP; SPINA BIFIDA ASSOC; MARCH OF DIMES FOUNDATION

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2013-417	01/16/2013 02/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRA TIRUVATTAR DR REDDY'S LABORATORIES INC	PHARMAFORCE - BROMFENAC SODIUM ANDA 02-030 SBA
2013-418	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K884834
2013-419	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112672
2013-420	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110030
2013-421	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030302
2013-422	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112198
2013-423	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070129
2013-424	01/17/2013 02/15/2013	CVM/OCD/	SAYED AHMED PFIZER ANIMAL HEALTH	ZILPATEROL TYPE B AND TYPE C FEED ASSAY METHODS; TIAMULIN TYPE B AND TYPE C FEED ASSAY METHODS; MONENSIN TYPE B AND TYPE C FEED ASSAY METHODS
2013-425	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103668
2013-426	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101030
2013-427	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030618
2013-428	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K083330
2013-429	01/17/2013 02/15/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	2012-4834, 2012-5151, 2012-5152, ETC
2013-430	01/17/2013 02/15/2013	FDA/OC/OES/DFOI/	KYLE SAMPSON HUNTON & WILLIAMS LLP	MYLAN LABORATORIES INC - FOI REQUESTS REGARDING WARNING LTR 10/31/11
2013-431	01/17/2013 02/15/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/	JORDAN FEIN UNITE HERE	XYIENCE ENERGY DRINK, SUPPLEMENTS - CMLPNTS, RPTS, CORR, ETC

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		ORA/		
2013-432	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	LEX PEARCE ICU MEDICAL INC	BECTON DICKINSON & CO - CLOSED ATINEOPLASTIC AND HAZARDOUS RECONSTITUTION AND TRANSFER SYS K123213
2013-433	01/17/2013 02/15/2013	ORA/ ORA/	DOUGLAS N BLUE II ZETETIC INC	STARBURST, CHEWING GUM, SKITTLES ENTRY #AV300384136 - RECS
2013-434	01/17/2013 02/15/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N BLUE II ZETETIC INC	IINFANT FORMULA ENTRY #DP406171638 - RECS
2013-435	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K012366
2013-436	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K090240
2013-437	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K992304
2013-438	01/17/2013 02/15/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ ORA/ ORA/ ORA/ ORA/	Doe J	DIETARY SUPPLEMENT WOW - LAB RPT
2013-439	01/17/2013 02/15/2013	OM/OMP/DODM/	BAYER, RANGE (RICHARD) D	DKT 2011D-0722
2013-440	01/17/2013 02/15/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHN WALSH JAMES ALEXANDER CORP	MOD-PAC, BUFFALO, NY - EIRS, 483S, RECALL RECS 1/11 TO PRESENT
2013-441	01/17/2013 02/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	STEWART, JAMES M	ETHYL ALCOHOL, TRICLOSAN, CHLOROXYLENOL - SAFETY RECS
2013-442	01/17/2013 02/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BELLWYCK PACKAGING SOLUTIONS, MISSISSAUGA, ONTARIO - EIR MOST RECENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-443	01/17/2013 02/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	CILAG AG, SCHAFFHAUSEN, SWITZERLAND - EIR 2010
2013-444	01/17/2013 02/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	CATALENT UK SWINDON ZYDIS LTD, SWINDON, WILTSHIRE - EIR 11/11
2013-445	01/17/2013 02/15/2013	FDA/OF/CFSAN/OCD/EOS/	CHASTINE 12B2563, JAMES	SODIUM CASEINATE - LIST OF INGREDIENTS
2013-446	01/17/2013 02/15/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	CTP FOIA REQUESTS 2010-2012
2013-447	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	WEIJIA DAI UNIVERSITY OF MARYLAND	EARLY COLLABORATION MEETINGS FOR PMA
2013-448	01/17/2013 02/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	WEIJIA DAI UNIVERSITY OF MARYLAND	PMA, 510K - DATA ON WITHDRAWN AND DENIED APPLICATIONS
2013-449	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kim Finch CHOICE SPINE LP	510KS - INDICATIONS FOR USE, DEVICE DESCRIPTION, SUBSTANTIAL EQUIVALENCE ETC
2013-450	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tonya Sausser Tarsa Therapeutics Inc.	SANDOZ GMBH, KUNDL, AUSTRIA - 483 (10/01/2012 - 11/01/2012)
2013-451	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Brent Ardaugh Framingham Heart Study	K004043
2013-452	01/18/2013 02/19/2013	CVM/OCD/ ORA/ ORA/	Abigail Sterling KPIX/CBS5	CHICKEN JERKY TREATS FOR DOGS - INTERNAL MEMOS
2013-453	01/18/2013 02/19/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Linda Bowen SANOFI	CAPSUGEL, GREENWOOD, SC - EIR JUNE 2012
2013-454	01/18/2013	FDA/OMPT/CTP/OD/	Desmond Jenson	CTP FOIA REQUEST LOG (08/22/2012 - 01/17/2013)

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	02/19/2013		Public Health Law Center	
2013-455	01/18/2013 02/19/2013	OM/OMP/DODM/	Desmond Jenson Public Health Law Center	FDA-2012-N-1148
2013-456	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	ISOLYTE E (NDA 019718)
2013-457	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Ensign Ensign, Jennifer D	ANDA APPLICATION FOR GENERIC 1G MESALAMINE SUPPOSITORY COMPARISON TO THE BRAND DRUG CANASA FILED BY SANDOZ IN 2007
2013-458	01/18/2013 02/19/2013	ORA/ORM/ ORA/ORM/	David Mangione FDAZILLA	LIST OF INSPECTIONS (11/01/2011 - 01/15/2013)
2013-459	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Larry Morris MORRIS, LARRY	THALLIUM CHLORIDE - CLINICAL TRIAL STUDIES INCLUDING SIDE EFFECTS
2013-460	01/18/2013 02/19/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	John Beasley MedTech Review, LLC	OSCOR, INC, PALM HARBOR, FL - 483, RESPONSES (07/27/2010 - 08/31/2010)
2013-461	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	David Weissburg OSS Bo	K953339, K915774, K051879
2013-462	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Norrington, PharmD, BCPS Clark Memorial Hospital Pharmacy	LEVOFLOXACIN AND AMIODARONE - REPORTED CASES OF TORSADES AND OTHER SERIOUS CARDIAC ARYTHMIAS
2013-463	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	Christopher Weaver THE WALL STREET JOURNAL	REATA PHARMACEUTICALS INC, BARDOXOLONE, UNIVERSITY OF TEXAS MEDICAL CENTER - FOIA REQUESTS
2013-464	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-465	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-466	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIC INC	CLOSED FOIA REQUESTS 12/31/12-1/4/13

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2013-467	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-468	01/18/2013 02/19/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 12/31/12-1/4/13
2013-469	01/18/2013 02/19/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	BRENDA M GARTZ ELI LILLY & CO	CLARITA KETELS, ST CLAIR SHORES, MI - 483 10/24/11
2013-470	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	HAMELN PHARMACEUTICALS GMBH, HAMELN, GERMANY - 483 6/4/12
2013-471	01/18/2013 02/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRED FIORE HYDROFERA LLC	HYDROFERA, WILLIMANTIC, CT - WOUND CARE PRODS K013462, K023138
2013-472	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	ANDERSON, CARL.	INJECTABLE PEPTIDES - MARKETING & SALES RECS, COMM
2013-473	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	ANDERSON, CARL.	PEPTIDELELABS.COM - ANABOLIC STEROIDS OR HUMAN GROWTH HORMONE COMM 1/11 TO PRESENT
2013-474	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLAUDINE Q HOMOLASH SHELLER LAW OFCS	PROTOCOL INH-189-003 - MEDWATCH FILINGS
2013-475	01/18/2013 02/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANNE GIGORGIO THERAVANCE INC	REGLAN (METOCLOPRAMIDE HCL) NDA 17-854, NDA 17-862 - SBA

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2013-476	01/18/2013 02/19/2013	FDA/OF/CFSAN/OCD/EOS/	REBECCA LL DANNENBERG FRANKLIN & PROKOPIK	PHUSION PROJECTS - FOUR LOKO WARNING LTR INVESTIGATION, Cmplnts, Rulings, Etc 11/10
2013-477	01/18/2013 02/19/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/	AIMEE DOYLE, ESQ. KOTCHEN & LOW LLP	BLIS TECHNOLOGIES LTD, FRUTARON LTD - FORMS 7512, 3499, MISBRANDING & UNAPPROVED NEW DRUG, ETC
2013-478	01/18/2013 02/19/2013	CVM/OCD/	TIM SCHWAB Food & Water Watch	AQUABOUNTY - NADA LTR
2013-479	01/18/2013 02/19/2013	FDA/OF/CFSAN/OCD/EOS/	ERIC F GREENBERG ERIC F GREENBERG PC	CHOCO TREASURE LLC OR CANDY TREASURE LLC, ETC - CHOCOLATE SURPRISE EGG (SURPRISE EGG OR CHOCO TREASURE) SUBMISSIONS, CORR, RVWS LAST 4 YRS
2013-480	01/22/2013 02/20/2013	FDA/OF/CFSAN/OCD/EOS/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	WAL-MART STORE'S INC - GREAT VALUE ENERGY SHOT CAERS
2013-481	01/22/2013 02/20/2013	FDA/OF/CFSAN/OCD/EOS/	BETHANY KENNEDY EMORD & ASSOCIATES, P.C.	COSTCO WHOLESALE CORP - KIRKLAND SIGNATURE ENERGY SHOT CAERS
2013-482	01/22/2013 02/20/2013	FDA/OF/CFSAN/OCD/EOS/	RICHARD E GUTTING JR REDMON PEYTON & BRASWELL LLP	ANTARTIC TOOTHFISH (DISSOSTICHUS MAWSONI) - MARKET NAMES RECS
2013-483	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ECKHARD MILSMANN PHD DIAPHARM GMBH & CO KG	HAMELN PHARMACEUTICALS GMBH - 483 6/4-14/12
2013-484	01/22/2013 02/20/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	NATURALLY TE - BLACK BOX WARNING, REGULATORY HISTORY, RECALL RECS
2013-485	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LORI PFOHL TELEFLEX MEDICAL	MELKER EMERGENCY CRICOTHYROTOMY CATHETER KIT K013916
2013-486	01/22/2013	ORA/		PHARMEDIUM SERVICES LLC - WARNING LTRS, EIRS, 483S, ETC 2010 TO PRESENT; AMERIDOSE LLC - EIR

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	02/20/2013	ORA/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KYRIAKIDIS, JOANNA	7/21/08, ETC
2013-487	01/22/2013 02/20/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	MARLA F MUNOZ SEADCO USA CORP	FROZEN PASTEURIZED EXTRA JUMBO SEADCO U-130, EXTRA JUMBO MARISSIMO U-250 ENTRY #E49-0022287-7 - LAB RESULTS
2013-488	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT #JY1512/L-27, SEAN	AMBIEN, SEROQUEL - AERS
2013-489	01/22/2013 02/20/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	ANTOINETTE PERRY ADAMMAS CONSULTING LLC	PAREXEL/PERCEPTIVE, BILERICA, MA - EIRS, 483S, CO RESP 2/14-23/12
2013-490	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Innetta Walker ESTECH	K090385, K060721, K093679 ETC
2013-491	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Catherine Shachaf Orlucent	VIZILITE BLUE ORAL EXAMINATION - APPROVAL RECS
2013-492	01/22/2013 02/20/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Judy Sadler IU Health Goshen Hospital	IU HEALTH GOSHEN HOSPITAL - 483, EIR (11/01/2012 - 11/06/2012)
2013-493	01/22/2013 02/20/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA REQUEST LOG (01/14/2013 - 01/18/2013)
2013-494	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Madalyn Duncan Impact medical, LLC	K113399, K110086, K071035
2013-495	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Petranek Petranek, Jan	SINEQUAN - POST MARKETING SAFETY ISSUE RECS (01/01/2000 - 01/01/2013)
2013-496	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Petranek Petranek, Jan	SEROQUEL - POST MARKETING SAFETY ISSUE RECS (01/01/2000 - 01/01/2013)

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2013-497	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	michele hong michele hong	CRESTOR, ZOCOR, LIPITOR, ETC - SUPPLEMENTAL NEW DRUG APPLICATION PROCESS RECS
2013-498	01/22/2013 04/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Christopher Rush FDA Quality and Regulatory Consultants	CHRISTOPHER RUSH - BIMO INSPECTIONS (01/01/2002 - 01/01/2008)
2013-499	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mick Fenton Immunodiagnostic Systems Ltd	K070788
2013-500	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charlie Zhou Living Stream Food and Drug Consulting	QSYMIA CAPSULE - CMC AND BIOPHARMACEUTICAL REVIEW
2013-501	01/22/2013 02/20/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	LLOYD, INC, SHENANDOAH, IA - EIR (MAY 2012)
2013-502	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Walt Brittle FDA Compliance Help Desk Inc	LINA MEDICAL APS, GLOSTRUP, DENMARK - 483, EIR, CORR (01/01/2006 to 01/01/2013)
2013-503	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandie R Durrett Durrett, Brandie R	NUVIGIAL - AERS
2013-504	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bill Webster UNIVERSITY OF SYDNEY	GUIDELINES FOR REPRODUCTION STUDIES FOR SAFETY EVALUATION OF DRUGS FOR HUMAN USE (1966)
2013-505	01/22/2013 02/20/2013	ORA/ ORA/	Richard O. Wood the Wood Burditt group	144-4574669-8 - LAB RESULTS
2013-506	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Benjamin Drosman REGENERON PHARMACEUTICALS INC	LUCENTIS - APPROVAL PACKAGE
2013-507	01/22/2013 02/20/2013	CVM/OCD/ ORA/	Steven A Roach FOOD ANIMAL CONCERNS TRUST	Date Range: 08/01/2001 - 01/14/2013; Records related to the feed investigation of a domestic United States cow that was reported as infected with Bovine Spongiform Encephalopathy on

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		ORA/ FDA/OC/OES/DFOI/		April 24, 2012. Specifically records related to the firm described as "One facility processed and manufactured with poultry waste in the report "Final Feed Investigation Summary - California BSE Case - July 2012" which is available on the FDA website. The focus of our request is whether or not the infected cow was likely exposed to ruminant meat and bone meal through the feeding of the form of poultry waste known as poultry litter. In addition we would like to better understand FDAs risk communication about the feed particularly how FDA chose to communicate to the public whether or not the cow was actually exposed to ruminant meat and bone meal through poultry litter. A more detailed request and a request for a fee waiver are included in the attached file. The wide date range of records is aimed at capturing feed investigations that occurred during the life of the cow, but before it was identified as being infected. ;
2013-508	01/22/2013 02/20/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO ESTABLISHMENT REGISTRATIONS AND TOBACCO PRODUCT LISTINGS
2013-509	01/22/2013 02/20/2013	FDA/OF/CFSAN/OCD/EOS/	Brian Kennedy AYER CAPITAL	MONSTER BEVERAGE - EMAILS, SLIDES, OTHER RECS RE 11/30/12 MEETING WITH FDA
2013-510	01/22/2013 02/20/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky KOWINSKY, BARBARA	THIBIANT INTERNATIONAL - EIR, WARNING LETTER, 483 (01/01/2012 - 01/11/2013)
2013-511	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	DYMISTA - SBA 202236 000
2013-512	01/22/2013 02/20/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JOSE HERNANDEZ - 483 (01/01/10 TO PRESENT)
2013-513	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110699
2013-514	01/22/2013 02/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121194
2013-515	01/22/2013 02/20/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Bayer HealthCare LLC Animal Health (Ruth Lamley) Bayer HealthCare LLC Animal Health	BOEHRINGER INGELHEIM, ELWOOD, KS - 483, EIR (4/2/2010, 11/23/2009, 11/6/2008, ETC)
2013-516	01/22/2013 02/20/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURE'S WAY/SCHWABE NORTH AMERICA - CORR WITH FDA

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2013-517	01/22/2013 02/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gen Li personal use	CLINICAL INVESTIGATOR DATA - FORM 1572 HUMAN DRUGS
2013-518	01/23/2013 02/21/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT FDA-2006-P-0007, FDA-2007-D-0433, ETC.
2013-519	01/23/2013 02/21/2013	OC/OM/OMP/DDM/	WESILEY ALBUQUERQUE NATIONAL CORPORATE RESEARCH	OTC VOL. 070280, 070270, 070238, ETC.
2013-520	01/23/2013 02/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam S. Morgenthau, MD MOUNT SINAI MEDICAL CENTER	KVIEM-SILTZBACH SKIN TEST - IND
2013-521	01/23/2013 02/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	VYVANSE - FAERS 6601306, 6615751, 6650425 ETC
2013-522	01/23/2013 02/21/2013	CVM/OCD/	Ruth Lamley Bayer HealthCare LLC Animal Health	GRINDEX, LATVIA - 483, EIR (04/27/2007)
2013-523	01/23/2013 02/21/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	Robert Haggerty, Sr. VP Corporate QA/QC Lyophilization Services of New England	LYOPHILIZATION SERVICES OF NEW ENGLAND, BEDFORD, NH - EIR UNREDACTED (06/02/2011 - 06/09/2011)
2013-524	01/23/2013 02/21/2013	FDA/OGROP/ORAN/SE-FO/FLA-DO/FLA-CB/	Lauren Farruggia Hyman, Phelps and McNamara	TG UNITED, INC, BROOKSVILLE, FL - 483, EIR WARNING LETTERS, ETC
2013-525	01/23/2013 02/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	ISR 4457069-8, 3197882-0, 5874061-7 ETC

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-526	01/23/2013 02/21/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Carole Kempfer RADIANT RESEARCH	DYNAVAX - INSPECTION REPORT (10/18/2012 - 11/16/2012)
2013-527	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 12/31/12-1/4/13
2013-528	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 12/3/12-1/4/13
2013-529	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DEBI COHEN CanReg, Inc.	FOI DAILY LOG 12/3/12-1/4/13
2013-530	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	WILLIAM A OLSON Center for Regulatory Services, Inc.	FOI DAILY LOG 12/31/12-1/4/13
2013-531	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 12/31/12-1/07/13
2013-532	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 12/31/12-1/4/13
2013-533	01/23/2013 02/21/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 12/31/12-1/4/13
2013-534	01/23/2013 02/21/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	CHOCOLATES SMLU3185964A - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2013-535	01/23/2013 02/21/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	CHOCOLATES SMLU3152799A - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2013-536	01/23/2013 02/21/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ ORA/ ORA/	DONALD N BLUE ZETETIC	CHOCOLATES SMLU3179805A - PHOTOGRAPHS, OASIS SCREEN SHOTS, CBP FORM 3461
2013-537	01/23/2013 02/21/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	PAUL W TRIPP LINCARE INC	THH ACQUISTION LLC (TOTAL HOME HEALTH) - EIRS. 483S, WARNING LTRS 1/04 TO PRESENT
2013-538	01/23/2013	FDA/OMPT/CDER/ORP/DIDP/	Carol Wasteney	ROHTO-MENTHOLATUM, THUAN AN TOWN, VIETNAM - EIR

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	02/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	The Mentholatum Company	(05/15/12 TO 01/22/2013)
2013-539	01/23/2013 02/21/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Doe J	INDIVIDUAL RECS
2013-540	01/23/2013 02/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MERCK - ZOSTAVAX FINAL PROTOCOL, RPTS 11/06.5/07, 11/10, 5/11
2013-541	01/24/2013 02/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gary Koenig Gary Koenig	BAXTER TISSEAL - 510K
2013-542	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shannon James Northern Navajo Medical Center	ANCEF - APPROVAL HISTORY; LABELING REVISION HISTORY
2013-543	01/24/2013 02/22/2013	OM/OMP/DODM/	Michael Slater Merrimack Pharmaceuticals, Inc.	DOXORUBICIN HYDROCHLORIDE - COMMENTS ON DRAFT GUIDANCE
2013-544	01/24/2013 02/22/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	LSNE, BEDFORD, NH - EIR (6/2/11)
2013-545	01/24/2013 02/22/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE IRB - 483, RESPONSE (01/07/11)
2013-546	01/24/2013 02/22/2013	FDA/OF/CFSAN/OCD/EOS/	Murray Carpenter Murray Carpenter	STARBUCKS COFFEE, TEA - CAERS (01/01/2004 - 12/31/2012)
2013-547	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2013-548	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202292
2013-549	01/24/2013 02/22/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/	Michael Atkins Atkins Intellectual Property, PLLC	B&B INTERNATIONAL, LINDEN, NJ - PACKING PERMITS AND RECS

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		ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/		
2013-550	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Dustin Block IPD Analytics, LLC	ANDA 079040 - EFFECTIVE APPROVAL LETTER
2013-551	01/24/2013 02/22/2013	FDA/OC/OES/DFOI/	MUJIB U. QIDWAI GRIFOLS BIOLOGICALS INC	OCTAPHARMA AB, STOCKHOLM, SWEDEN - EIR, 483 1/11
2013-552	01/24/2013 02/22/2013	FDA/OC/OES/DFOI/	MUJIB U. QUIWAI GRIFOLS BIOLOGICALS INC	CSL BEHRING, VICTORIA, AUSTRALIA - EIR, 483 1/10 TO 12/31/12
2013-553	01/24/2013 02/22/2013		BRENDA M. GARTZ ELI LILLY & CO	RECORDATI, CAMPOVERDE, ITALY - EIR 7/10
2013-554	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	JANSSEN BIOLOGICS, LEIDEN, NETHERLANDS - EIR MOST RECENT
2013-555	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	DAITO PHARMACEUTICAL CO LTD, TOYAMA CITY, JAPAN - EIR 9/11
2013-556	01/24/2013 02/22/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	PATRICIA L. REGENYE Celgene Corporation	ANNELIESE GONZALEZ, CORPUS CHRISTI, TX - 483 11/08 TO PRESENT
2013-557	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	MUHAMMAD SALIM, ALLAN BLAIR CANCER CTR, REGINA, CANADA - 483 12/03 TO PRESENT
2013-558	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	CAROLYN L. WAGNER CARESTREAM HEALTH INC	SHIMADZU CORP - DAR7000 RADSPED SAFIRE K050925
2013-559	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	CAROLYN L. WAGNER CARESTREAM HEALTH INC	FUJIFILM SYSTEMS USA INC - FDR ACCELERATE STATIONARY XRAY SYS K093427
2013-560	01/24/2013	CVM/OCD/	KRISTI O. SMEDLEY, Ph.D.	FAP OA4200

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	02/22/2013		Center for Regulatory Services, Inc.	
2013-561	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SMITH, KIMBERLY .	XTANDI A - AER
2013-562	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSSMAN, MARVIN L	RADIONICS MEDICAL INC - SPECTRUM ANALYZER 8000 K810851
2013-563	01/24/2013 03/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RICHARD	BLOOD PRODCUTS A/C BPAC 9/10/08, 7/27/10, 4/29/11
2013-564	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROXANNE OZAWA AFFYMAX INC	AUDREY GUREVICH, ST PETERSBURG MEDICAL ACADEMY, ST PETERSBURG, RUSSIA - EIR 12/11
2013-565	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROXANNE OZAWA COULON AFFYMAX INC	DR KONSTATIN GUREVICH, ST ELIZABETH CITH HOSPITAL, ST PETERSBURG, RUSSIA - 483, EIR 11/11
2013-566	01/24/2013 02/22/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	ROXANNE OZAWA COULON AFFYMAX INC	AFFYMAX INC, PALO ALTO, CA - EIR 10/11
2013-567	01/24/2013 02/22/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	ROXANNE OZAWA COULON AFFYMAX INC	EDOUARD MARTIN, MD, FLORIDA RESEARCH INSTITUTE, LAUDERDALE LAKES, FL - 483, EIR 9/11
2013-568	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L. ROSEN FOLEY & LARDNER LLP	SOFGEN PHARMACEUTICALS - PROGESTERONE ORAL CAPSULES ANDA 200456
2013-569	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID L. ROSEN FOLEY & LARDNER LLP	TEVA PHARMACEUTICALS - PROGESTERONE ORLA CAPSULES SBA ANDA 202121
2013-570	01/24/2013 02/22/2013	FDA/OF/CFSAN/OCD/EOS/	FREDERICK A. STEARNS Keller and Heckman LLP	NONO LABORATORIES INC GRASP 5G0297
2013-571	01/24/2013 02/22/2013	FDA/OF/CFSAN/OCD/EOS/	KELLY STAROSTA HILL Keller and Heckman LLP	STARLINGER & CO - NOL 160

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2013-572	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND & ASSOCIATES LLC	SILVERLON - CONTACT WOUND DRESSING K981299; WOUND PACKING STRIPS K984210
2013-573	01/24/2013 02/22/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	TIMOTHY P. COON, Esq. WILK AUSLANDER	CORR BETWEEN FDA & MIRA INC 9/11 TO 12/12
2013-574	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BORIS REYDEL, MD INVENTIO LLC	K112698
2013-575	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BORIS REYDEL, MD INVENTIO LLC	K112698 UNREDACTED
2013-576	01/24/2013 02/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE PURCELL DOCUTRIEVAL INFORMATION SERVICES	MINIVELLE NDA 03-752 SBA
2013-577	01/24/2013 02/22/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	PATRICIO T.D. BARRERA BARRERA & ASSOCIATES	KRAMER LABORATORIES INC - EXHIBITS, ATTACHMENTS
2013-578	01/24/2013 02/22/2013	CVM/OCD/ OM/OMP/DODM/	GABRIEL SCOTT CASCADIA WILDLANDS	DCK FDA 2011-N-0899
2013-579	01/24/2013 02/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	BRADFORD P. KLAGER LAW OFFICES OF DOUGLAS A ALLISON	MI GWANG POLYMACON CONTACT LENSES - CORR
2013-580	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Javier Collazo RespCare	K071560
2013-581	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Francine Vero Francine Vero -Towne, Ryan & Partners PC	NOVASURE INPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM - MANUALS, INSTRUCTIONS, TRAINING ETC
2013-582	01/25/2013 02/25/2013	CVM/OCD/	Application document for animal drug using nitenpyram SUMITOMO CHEMICAL CO LTD	NITENPYRAM - APPROVAL RECS
2013-583	01/25/2013 02/25/2013	FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/	Gene Partin ZOLL Lifecor Corporation	ZOLL LIFECORE CORPORATION - EIR EXHIBITS (08/28/2001 - 08/28/2001)
2013-584	01/25/2013 02/25/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	Azuka L. Uzoh Law Office of Azuka L. Uzoh	TEVA PARENTERAL MEDICINES, INC, IRVINE, CA - EIR, 483, SHUTDOWN ORDERS (08/02/2007 - 07/31/2010) (CERTIFIED)
2013-585	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maria Makarich Makarich, Maria	OXARBAZEPINE 300/5 SUSPENSION - BIOEQUIVALENCE DATA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-586	01/25/2013 02/25/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	AMELIA LANGSTON, ATLANTA, GA - 483, RESPONSE (08/01/2006 - 10/01/2006)
2013-587	01/25/2013 02/25/2013	ORA/ ORA/ ORA/OE/ ORA/OE/	Theresa Thompson UIC c/o Theresa Thompson	MEDICAL DEVICE AND RAD HEALTH RECALL EVENTS
2013-588	01/25/2013 02/25/2013	FDA/OF/CFSAN/OCD/EOS/	LaVeeta Moten LaVeeta Moten	NOTICE RE WORK ON LAPTOPS FROM COLLEGE PARK DESKTOP SUPPORT
2013-589	01/25/2013 02/25/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Sandy Stagge CTI Clinical Trial & Consulting Services	JEFFREY SOSMAN, MD - 483, RESPONSE (09/01/2010 - 12/01/2010)
2013-590	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K041711
2013-591	01/25/2013 02/25/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Jens Saakvitne South Dakota Lions Eye and Tissue Bank	LIFESOURCE, MINNEAPOLIS, MN - 483 (01/01/2011 - 12/31/2011)
2013-592	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 074731
2013-593	01/25/2013 02/26/2013	CVM/OCD/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Jeffrey Jones, Counsel for The Scotts Miracle-Gro Company The Scotts Miracle-Gro Company	SCOTT'S MIRACLE GRO COMPANY - TESTING RE HARM TO BIRDS, WILD BIRD FOOD, ETC
2013-594	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Walters AtriCure, Inc.	K101961, K111064
2013-595	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 075357

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-596	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 074924
2013-597	01/25/2013 02/25/2013	OM/OMP/DODM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bijal Pandhi NOVARTIS PHARMACEUTICAL CORP	SALMON CALCITONIN - ENDOCRINOLOGIC AND METABOLIC ADVISORY COMMITTEE MATERIALS 1991, 1994
2013-598	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	ANDA 074588
2013-599	01/25/2013 02/25/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Hillary M Estes NESTLE USA INC	NESTLE USA, ANDERSON, IN - EIR (05/14/2010 - 11/05/2010)
2013-600	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Javier Collazo Respacare	K102404
2013-601	01/25/2013 02/25/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Jeri Hill DMS Holding, Inc., DbA/Briggs Healthcare	DMS HOLDING, INC DBA BRIGGS HEALTHCARE, WAUKEGAN, IL - EIR (6/15/2011 - 06/16/2011)
2013-602	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anthony Lenza, Esq. Amabile & Erman, P.C.	265782, 10455-10-2002-00021, 1045510-2002-00027 ETC - MAUDE REPORTS AND INVESTIGATION RECS
2013-603	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Stagge CTI Clinical Trial & Consulting Services	JOHAN MAERTENS, BELGIUM - EIR (06/01/2004 - 08/30/2004)
2013-604	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	FDA RESPONSE TO 06/28/2001 LETTER FROM INTUITIVE SURGICAL
2013-605	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	UQUIFA, SPAIN; UQUIFA, MEXICO - EIR, 483, WARNING LETTER, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-606	01/25/2013 02/25/2013	FDA/OC/OES/DFOI/	DARREN L BROWN PROVOST UMPHREY LAW FIRM	DR ERIC WILHELMSSEN, WILHELMSSEN CONSULTING - GUIDANCE LTR ON INGREDIENT DECLARATION FOR VARIOUS SWEETENERS 5/8/00; HILLEL S ROBERTS, UPSCALE FOODS, INC - WARNING LTR 11/15/04, ETC (CERTIFIED)
2013-607	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRYAN #254638, T TERRELL	BUSPAR (BUSPICONE HCL) - MARKETING, SALES, MFG RECS
2013-608	01/25/2013 02/25/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANOSHIMA MD HOSPITAL FOR SICK CHILDREN	KEPPRA (LEVETIRACETAM) - AERS
2013-609	01/25/2013 02/25/2013		VIELHABER, LINDA	SAFETY RPT #1027508
2013-610	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY TAYLOR INFOTRIEVE INC	GUIDANCE FOR CLNCL EVALUATION OF COMBINATION ESTROGEN/PROGESTIN-CONTAINING DRUG PRODS
2013-611	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER L ROBINSON MORRISON & FOERSTER LLP	LEPU MEDICAL TECHNOLOGY (BEIJING) CO LTD - RADIAL ARTERY COMPRESSION TOURNIQUET K111837
2013-612	01/25/2013 02/25/2013	FDA/OF/CFSAN/OCD/EOS/	Jason DeYoung WESTERN MICHIGAN UNIVERSITY	FOOD AND BEVERAGE FIRMS IN MI, IN, OH - COMPANY NAMES, CONTACT, EMAIL ETC
2013-613	01/25/2013 02/25/2013	ORA/ ORA/	PETER D WEINSTEIN ESQ COLE SCOTT AND KISSANE	INFUPHARMA LLC, HOLLYWOOD, FL - INVESTIGATION RPT 1/17/12
2013-614	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	CAROL NAKAGAWA MERGE HEALTHCARE	AYCAN DIGITALSYSTEME GMBH - AYCAN MOBILE K122260
2013-615	01/25/2013 02/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ARIANNA OBERMEIER FLORIDA BLUE	ORANGE BOOK - EXCLUSIVITY AND PATENT FILES
2013-616	01/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	RENAE N FEO	JARIT ENDOSCOPES K944870

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	02/25/2013		INTEGRA YORK PA INC	
2013-617	01/25/2013 09/17/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	CRYSTAL SPIVEY WILDEMAN KAHN DEES DONOVAN & KAHN LLP	MEAD JOHNSON NUTRITION CO - ENFAMIL PREMIUM INFANT, ENFAMIL GENTLEASE, ENFAMIL AR RECS 2009 TO PRESENT
2013-618	01/25/2013 02/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	STEPHEN D ELLIS ELLIS BOXER & BLAKE PLLC	AADCO MEDICAL INC, RANDOLPH, VT - EIRS, WARNINGS, REGISTRATIONS, ETC
2013-619	01/25/2013 02/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	OFFICE OF IN VITRO DIAGNOSTIC DEVICE EVALUATION AND SAFETY (OIVD) - UNTITLED LTRS SENT TO A CLNCL LAB, LAB SELLING ANALYTE SPECIFIC REAGENTS (ASR), ETC
2013-620	01/25/2013 02/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ABEBE #285447, UNULA B	MAXZIDE, NAPROXEN, NIFEDIPINE, ETC - RECS
2013-621	01/25/2013 02/25/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHN D HENDERSON JOHN D HENDERSON PSC	SOUTHERN STATES CAMPBELLSVILLE SERVICE, CAMPBELLSVILLE, KY, HARGIS TRUCKING INC, COLUMBIA, KY - DELIVERY OF UREA CONTAMINATED FEED TO SMITH FARMS 12/09
2013-622	01/25/2013 02/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	MARSHA GREEN DANIEL POWELL & BREWER LLC	RAW CLOVER SPROUTS E COLI OUTBREAK AT JIMMY JOHN'S RESTAURANTS INVESTIGATION RECS 12/25/11 TO 3/3/12
2013-623	01/25/2013 02/25/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	SYNERGY HEALTH, SAN DIEGO, CA - EIR 2/12
2013-624	01/25/2013 02/25/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	ANDERSON PACKAGING, ROCKFORD, IL - EIR 4/18/12
2013-625	01/25/2013 02/25/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	APTUIT INC, KANSAS CITY, MO - EIR 3/24/10
2013-626	01/25/2013 02/25/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDA NEWS	FOI DAILY LOG 1/7-11/13
2013-627	01/25/2013 02/25/2013	FDA/OF/CFSAN/OCD/EOS/	JOHN R ERICKSON BASF CORP	CFSAN CANCER ASSESSMENT CIMMITTEE MEMO CAP 9C0096 4/21/89
2013-628	01/28/2013	FDA/OF/CFSAN/OCD/EOS/	Melissa Hirst	NURSERY WATER, WELL WATER - TESTING RECS;

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	02/26/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JONES DAY	COMPLAINT; ETC
2013-629	01/28/2013 02/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Chris Cano Agile Therapeutics	NORLESTRIN 21 2.5/50 - MEDICAL OFFICER REVIEW AND OTHER REVIEWS
2013-630	01/28/2013 02/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OM/DDM/	michele hong michele hong	NDA 21366 S10
2013-631	01/28/2013 02/26/2013	FDA/OF/CFSAN/OCD/EOS/	Chris Lahiff McDermott Will & Emery LLP	CONTAMINATED DRIED FRUITS - ADVERSE EVENTS (01/01/2000 - 01/25/2013)
2013-632	01/28/2013 02/26/2013	ORA/ ORA/	Janice M. Rizzi Radagast Pet Food, Inc.	CONSUMER COMPLAINT 129691
2013-633	01/28/2013 02/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Curtis Obert CASE WESTERN RESERVE UNIVERSITY	RADIATION EMITTING MACHINES IN HOSPITALS - NUMBER, INSTALATION
2013-634	01/28/2013 02/26/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Brian Roemer Gate Gourmet	GATE GOURMET - CONSUMER COMPLAINT RECS
2013-635	01/28/2013 02/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Chris Cano Agile Therapeutics	NORLESTRIN 21 1/50 - MEDICAL OFFICER REVIEW
2013-636	01/28/2013 02/26/2013	FDA/OF/CFSAN/OCD/EOS/	Zoi Pappayiannis N/A (CONSUMER)	MOLYBDENUM, NICKEL, COBALT, VANADIUM, AND STRONTIUM IN TOTAL DIET
2013-637	01/28/2013 02/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jennifer Brown INFOTRIEVE INC	PLACEBO-CONTROLLED CLINICAL TRIALS DATABASE FOR SUICIDALITY AND PREPARING DATA SETS FOR ANALYSIS

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2013-638	01/28/2013 02/26/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Travis J. Jacobs, Esq. The Jacobs Law, LLC	MANUKA HONEY, WEDDERSPOON ORGANIC - REPORTS, TEST RESULTS, APPLICATION, ETC (01/01/2005 - 01/25/2013)
2013-639	01/28/2013 02/26/2013	CVM/OCD/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Jason A. Forge Robbins, Geller, Rudman & Dowd	SCOTTS MIRACLE GRO - CORR WITH FDA RE RECALLS; TELEPHONE CALLS
2013-640	01/28/2013 03/14/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Gustafson PLASMA PROTEIN THERAPEUTICS ASSOCIATION	POST DONATION FATALITY REPORTS
2013-641	01/28/2013 02/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERAN BEN-TAL BIOCEP LTD	VERIDEX - CELL TRACKS AUTO PREP SYS K122821; K110406; K100684; IMMUNICON - CELL TRACKS AUTO PREP SYS K040077
2013-642	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOTT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	ARIAD PHARMACEUTICALS - RIDAFOROLIMUS SPA
2013-643	01/28/2013 02/26/2013	FDA/OF/CFSAN/OCD/EOS/	GREENBERG, BEATRICE .	FOOD LBLG POLICY REGARDING HUMAN FOOD 9/11 TO PRESENT
2013-644	01/28/2013 02/26/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	PATRICIA L. REGENYE Celgene Corporation	SHAKER DAKHIL, CA CTR KANSAS, WICHITA, KS - 483 3/12 TO PRESENT
2013-645	01/28/2013 02/26/2013	ORA/OE/ ORA/OE/	MARY CLARE JALONICK ASSOCIATED PRESS	SALMONELLA, E COLI, LISTERIA AT FOOD FACILITIES - 483S
2013-646	01/28/2013 02/26/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	ZIMMERER, CHARLES	APEX ENERGETICS INC, IRVINE, CA - RECS
2013-647	01/28/2013 02/26/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	ZIMMERER, CHARLES	ARMEN SIMONIAN, ORANGE COUNTY, CA - RECS
2013-648	01/28/2013 02/26/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	ZIMMERER, CHARLES	BLOOD NUTRITION INSTITUTE INC, SANTA ANA, CA - RECS

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2013-649	01/28/2013 02/26/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	PRINCIPAL LAB INC, SANTA ANA, CA - RECS
2013-650	01/28/2013 02/26/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	HEALTH SCIENCES INVESTMENT GROUP, PHOENIX, AZ - RECS
2013-651	01/28/2013 02/26/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	ARMOND SIMONIAN, ORANGE COUNTY, CA - RECS
2013-652	01/28/2013 02/26/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	CYREX LABORATORIES LLC, PHOENIX, AZ - RECS
2013-653	01/28/2013 02/26/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ZIMMERER, CHARLES	BLOOD NUTRITION SOFTWARE INC - RECS
2013-654	01/28/2013 02/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOBBS 134225, BRIAN	AMBIEN (ZOLPIDEM) - AERS
2013-655	01/28/2013 02/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAURA HOBBS LEXIS NEXIS COURTLINK INC	AMOUNT OF 14 HYDROXYCODEINONE PERMITTED IN OXYCODONE HCL ACTIVE PHARMACEUTICAL INGREDIENT (API) - RECS
2013-656	01/28/2013 02/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	NANETTE CANEPA BECKMAN COULTER INC	HEMOCCULT TEST FOR RECAL OCCULT BLOOD
2013-657	01/28/2013 03/12/2013	FDA/OGROP/ORAP/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/COS/OL/ OC/OCC/ ORA/ ORA/ OC/OL/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST CENTURY	CORR BETWEEN FDA COMMISSIONER, THE DEPUTY COMMISSIONER FOR FOODS AND VETERINARY MEDICINE, IVACARE CORP
2013-658	01/28/2013 02/26/2013	CVM/OCD/	DAN ASHE PATTERSON BELKNAP WEBB &	FELINE HAIRBALLS; FELINE UNIARY TRACT HEALTH - LBLG, NO OBJECTION LTRS

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			TYLER	
2013-659	01/28/2013 02/26/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	DOUGLAS N. BLUE ZETETIC	ENTRY NO AV300383518
2013-660	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLEEN KLASMEIER SIDLEY AUSTIN LLP	PFIZER INC - ZOLOFT WARNING LTR 8/1/96
2013-661	01/28/2013 03/05/2013	FDA/OO/OFBA/OAGS/	FOI Services, Inc.	ABBOTT LAB V797P-5057B; ELI LILLY V797P-2237D; GENENTECH V797P-5067B
2013-662	01/28/2013 02/26/2013	FDA/OC/OES/DFOI/	ERIN E. SEDER VENABLE LLP	AZO GESIC; AZO SEPTIC; AZO STANDARD - AER 2005 TO PRESENT
2013-663	01/28/2013 02/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S. REICHERTZ SHEPPARD MULLIN ET AL	VENOFER AER
2013-664	01/28/2013 02/26/2013	FDA/OC/OES/DFOI/	TRISH McGRADE PRITZKER OLSEN	SIMPLY THICK - NECROITIZING ENTEROCOLITIS INSP, RPTS, CORR 1/10 TO PRESENT
2013-665	01/28/2013 02/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ ORA/ ORA/ ORA/OE/ ORA/OE/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	J SCOTT NABERS BLIZZARD MCCARTHY & NABERS LLP	WYETH LABORATORIES INC, PFIZER INC - 483S, WARNING LTRS; EFFEXOR XR LBLG CHANGES, FINES, ETC

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2013-666	01/28/2013 02/26/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	SHERI O. COVINGTON K&L GATES	JK SUCRALOSE INC, EDISON, NJ - EIR, 483, WARNING LTR, CORR SINCE 2005
2013-667	01/28/2013 02/26/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	SHERI O. COVINGTON K&L GATES	JM HUBER CORP - EIR, 483, WARNING LTR, CORR SINCE 2005
2013-668	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	RE-LY (NCT 0262600), RELY-ABLE (NCT 00808060), TRIALS - EIRS, 483S, FDA FORM 1572
2013-669	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PRADAXA (DABIGATRAN) - APRVL PKG, A/C, AGENDAS, ETC
2013-670	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS - RELY-ABLE TRIAL RESULTS, RPTS 12/12
2013-671	01/29/2013 02/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS - RE-LY & RELY-ABLE TRIALS USER FEES; MERCK & CO INC - SHINGLES PREVENTION STUDY RVWS, USER FEES

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2013-672	01/29/2013 02/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	HERPES ZOSTER VACCINE - VAERS 283902, 316387, 277377, ETC
2013-673	01/29/2013 02/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVIS, DAWN	AKRIMAX - TIROSINT 50 MG CMLNT
2013-674	01/29/2013 02/27/2013	FDA/OF/CFSAN/OCDE/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANCISCO JAVIER DAVALOS FARRIMOND CASTILLO & BRESNAHAN PC	VIGOR-25 - MFR NAMES, CONTACT RECS, DISTRIBUTORS NAMES, ETC
2013-675	01/29/2013 02/27/2013	FDA/OC/OES/DFOI/	CHRIS WEAVER WALL STREET JOURNAL	2011-7792, 2011-7791, 2011-7790, ETC
2013-676	01/29/2013 02/27/2013	FDA/OC/OES/DFOI/	CAROLLO, RUSSELL	FOI DAILY LOG 1/03 TO PRESENT
2013-677	01/29/2013 02/27/2013	FDA/OC/OES/DFOI/	SCHONHOFT, BRAD	PFIZER INC, (ZOETIS), KALAMAZOO, MI - 483S, WARNINGS 1/1-25/13
2013-678	01/29/2013 02/27/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	MOLLY SHEARER UNITEHERE!	GATE GOURMET, BOSTON, MA, NEW YORK, NY, ELIZABETH, NJ, ETC - AIRPORT KITCHEN EIRS, VIOLATIONS, CMLNTS RPTS, ETC

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2013-679	01/29/2013 02/27/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	DAVID B SUDZUS DRINKER BIDDLE REATH LLP	MARLENE LANTZ, MCHENRY COUNTY, IL, FDA CHICAGO FIELD OFFICE - MEMOS, MTG MINS, SUMMARIES, ETC 2005
2013-680	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	7345315, 7389965, 7419534 ETC - FAERS DETAILED RPTS
2013-681	01/30/2013 02/28/2013	CVM/OCD/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Ryan T. Kearney COZEN O'CONNOR	MILO'S KITCHEN CHICKEN JERKY RECALL - INSPECTIONS, TESTING, RECALL RECS, ETC
2013-682	01/30/2013 03/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/	B Burges BURGESS, BERNIE	INTERNAL CORR RE CLINICAL TRIAL COMPLAINT
2013-683	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	b. Burges BURGESS, BERNIE	FACTS ASSIGNMENT 808885 - TRAVEL VOUCHERS, RECEIPTS, EXPENSES, ETC
2013-684	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b burges BURGESS, BERNIE	PROTOCOL, BACKGROUND INFORMATION SENT TO DISTRICT OFFICE FOR FACTS ASSIGNMENT 808885

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-685	01/30/2013 02/28/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS (01/04/2013 - 01/28/2013)
2013-686	01/30/2013 02/28/2013	ORA/OCI/ ORA/OCI/	Doe J	INDIVIDUAL RECS
2013-687	01/30/2013 02/28/2013	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2013-688	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	b. burgess BURGESS, BERNIE	CORR RE CSO AND SUPERVISOR FOR FACTS ASSIGNMENT 808885
2013-689	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Alexander Barney The Karmel Law Firm	HILL-ROM, INC, BATESVILLE, IN - INSPECTION RECS (03/01/2011 - 1/28/13)
2013-690	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeff Overley Law360	RANBAXY ATORVASTATIN - AERS (11/01/2012 - 01/28/2013)
2013-691	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (01/21/2013 - 01/25/2013)
2013-692	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lynn Walsh WPTV 5	NUVARING, YAZ, YASMIN - AERS (01/01/2009 - 01/28/2013)
2013-693	01/30/2013 02/28/2013	ORA/ ORA/	David Hanson N/A	NUTRO PET FOOD - LAB RESULTS SINCE JAN 2012
2013-694	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Courtney Burgess Sugarman & Sugarman, P.C.	SCULTPRA - PACKAGE AND PRODUCT INSERTS (01/01/2009 - 01/28/2013)

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		FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-695	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Gonnello FARUQI & FARUQI LLP	AETERNA ZENTARIS INC, KERYX BIOPHARMACEUTICALS - PHASE 2 AND PHASE 3 TRIALS TESTING PERIFOSINE FOR TREATMENT OF COLORECTAL CANCER
2013-696	01/30/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Anne-Solenne Rolland Sutton Law Group, P.A.	VACCINE LOT NUMBERS R05172, 471804, 469395
2013-697	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bob Bowers OBT	K112946
2013-698	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jim Petricek Harpeth Advisors	OSTEOCEL, TRINITY - AERS
2013-699	01/30/2013 02/28/2013	FDA/OO/OHR/	Doe J	INDIVIDUAL RECS
2013-700	01/30/2013 02/28/2013	OM/OMP/DODM/	Kathryn del Real The Cavanagh Law Firm	GUIDE TO INFORMED CONSENT - INFORMATION SHEET 2004
2013-701	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Lotito Biotechnology Dashboard	PREDNISONE - AERS (01/01/2012 - 01/28/2013)
2013-702	01/30/2013 02/28/2013	FDA/OF/CFSAN/OCDE/EOS/	Rachel Johnson FOI Services, Inc.	FCN 725
2013-703	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Sill Intezyne	IND 104117 - CORR
2013-704	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113188
2013-705	01/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K090995

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	02/28/2013		FOI Services, Inc.	
2013-706	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K112994
2013-707	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kevin Sill Intezyne	IND 104861 - CORR
2013-708	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K854334
2013-709	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 74531 S1
2013-710	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 091328
2013-711	01/30/2013 02/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeff Wurtsbaugh PromoLogics, Inc.	K922187
2013-712	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Krista Brown (Pharmacist) Krista Brown (pharmacist, BRHA)	QUETIAPINE - AERS
2013-713	01/30/2013 02/28/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ CVM/OCD/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Ryan T. Kearney COZEN O'CONNOR	IMS TRADING CORP - INSPECTIONS, INVESTIGATIONS, RECALLS ETC
2013-714	01/30/2013 02/28/2013	CVM/OCD/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Ryan T. Kearney COZEN O'CONNOR	WAGGIN TRAIN, CANYON CREEK - INSPECTIONS, INVESTIGATIONS, RECALLS ETC

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		FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/		
2013-715	01/30/2013 02/28/2013	CVM/OCD/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Ryan T. Kearney COZEN O'CONNOR	CADET CHICKEN JERKY PET TREATS - INSPECTION, INVESTIGATION, TESTING ETC
2013-716	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BORON, MELANIE	VASCEPA (ICOSAPENT ETHYL) - PHARMACODYNAMIC & PHARMACOKINETIC DATA, PHASE 1 & PHASE 2 TESTING, ETC
2013-717	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE CORP - EXCHANGE TRANSFUSION TRAY PROCEDURE TRAY FDA FORM 3500A, RPTS, MEMOS, ETC
2013-718	01/30/2013 02/28/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OF/CFSAN/OCD/EOS/	CLAUDIA NUNN BURDOCK GROUP	ALOE VERA - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-719	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	TRAVIS SCHAFTENAAR UBS GLOBAL ASSET MANAGEMENT	HILL-ROMM, BATESVILLE, IN - 483S 10/12, 11/12
2013-720	01/30/2013 02/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH M LANE MD HOSPITAL FOR SPECIAL SURGERY	DENOSUMAB BLA 125320 - APRVL RECS
2013-721	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	THOMPSON, RAY	AKORN INC, DECATUR, IL 5/14-25/12; ABBOTT MOLECULAR, DES PLAINES, IL 7/2-11/12; BIOSYNERGY INC, ELK GROVE VILLAGE, IL 2/27/12-3/2/12, ETC - 483S
2013-722	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	THOMPSON, RAY	PAIN MANAGEMENT TECHNOLOGIES INC, AKRON, OH 6/4-8/12; CASCO MANUFACTURING SOLUTIONS INC, CINCINNATI, OH 5/7-10/12; REESE PHARMACEUTICAL CO, CLEVELAND, OH 12/14/11-1/11/12, ETC - 483S
2013-723	01/30/2013 02/28/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	THOMPSON, RAY	KIMBERLY CLARK CORP, CONWAY, AR 4/23-27/12; ENCOMPASS GROUP LLC, ADDISON, TX 1/18-20/12; MISSION PHARMACAL CO, BOERNE, TX 5/9-25/12. ETC - 483S
2013-724	01/30/2013 02/28/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	THOMPSON, RAY	ACELLA PHARMACEUTICALS LLC, ALPHARETTA, GA 3/19-22/12; REMINGTON MEDICAL INC, ALPHARETTA, GA 5/21/12-6/6/12; BANNER PHARMACAPS INC, HIGH POINT, NC 6/25/12-7/2/12, ETC - 483S

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2013-725	01/30/2013 02/28/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	PETNET SOLUTIONS INC - EIRS, 483S, CO RESP 2/12
2013-726	01/30/2013 02/28/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	BECTON DICKINSON MEDICAL SYSTEMS, CANAAN, CT 3/14-16/12; PFIZER INC, GROTON, CT 2/21-24/12; Z-MEDICA CORP, WALLINGFORD, CT 3/29/12-4/11/12, ETC - 483S
2013-727	01/30/2013 02/28/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY 3/15-19/12; AMNEAL PAHRMACEUTICALS OF NEW YORK LLC, HAUPPAUGE, NY 5/8-15/12; FOREST LABORATORIES INC, COMMACK, NY 2/15-22/12, ETC - 483S
2013-728	01/30/2013 02/28/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMPSON, RAY	CIANNA MEDICAL INC, ALISO VIEJO, CA 12/14/11-1/9/12; REVITOL CORP, BURBANK, CA 4/24/12-6/1/12; PURQUALITY LLC, TEMPE, AZ 1/10-30/12, ETC - 483S
2013-729	01/30/2013 02/28/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	THOMPSON, RAY	PHARMATEC LLC, DAVIE, FL 1/12-24/12; BECKMAN COULTER INC, HIALEAH, FL 7/16-20/12; PACE TECH INC, CLEARWATER, FL 3/15-19/12, ETC - 483S
2013-730	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	2012-7518
2013-731	01/30/2013 02/28/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ST MARY'S HOSPITAL & MEDICAL CENTER INC, GRAND JUNCTION, CO - EIRS, 483S, CO RESP 6/4-15/12
2013-732	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TAIWAN THREE MAST PHARMACEUTICAL CO LTD, TAINAN CITY, TAIWAN - EIRS, 483S, CO RESP 4/23-27/12
2013-733	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	THOMPSON, RAY	APHENA PHARMA SOLUTIONS-MARYLAND LLC, EASTON, MD 1/9-13/12; MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV 1/23/12-2/2/12; BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA 3/22/12-4/4/12 - 483S
2013-734	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	RUGER CHEMICAL, LINDEN, NJ - EIRS, 483S, CO RESP 9/22/11-10/11/11
2013-735	01/30/2013 02/28/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	AMGEN INC, BOULDER, CO 12/14/11-1/6/12; ADAPTA MEDICAL INC, COLORADO SPRINGS, CO 1/23-26/12; NELSON LABORATORIES INC, SALT LAKE CITY, UT 3/5-9/12, ETC - 483S
2013-736	01/30/2013 02/28/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	GLOBUS MEDICAL INC, AUDUBON, PA 4/18/12-5/1/12; AUXILIUM PHARMACEUTICALS INC, HORSHAM, PA 6/25/12-7/6/12; MUTUAL PHARMACEUTICAL CO INC 1/9-27/12, ETC - 483S
2013-737	01/30/2013	FDA/OGROP/ORASE-FO/NOL-		SAGE PHARMACEUTICALS INC, SHREVEPORT, LA 2/14-

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	02/28/2013	DO/NOL-CB/	THOMPSON, RAY	17/12; HAWTHORN PHARMACEUTICALS INC, MADISON, MS 1/30/12-2/15/12; ONYX MEDICAL CORP, LMEMPHIS, TN 2/1-13/12, ETC - 483S
2013-738	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	MIRGEN PHARMACEUTICAL, BOISE, ID 1/9-30/12; GENETECH INC, HILLSBORO, OR 6/19-27/12; GYNEX CORP, REDMOND, WA 7/16-20/12, ETC - 483S
2013-739	01/30/2013 02/28/2013	ORA/ORM/ ORA/ORM/	THOMPSON, RAY	HUMAN DRUG, MEDICAL DVC FIRMS - GMP, GLP, GCP INSPS 8/1/12-12/31/12
2013-740	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	HERBRAND PHARMACHEMICALS GMBH, GENGENBACH, GERMANY 6/11-15/12; SCICAN BHT, GERSTHOFEN, GERMANY 7/16-19/12; BASF PHARMACHEMIKALIEN GMBH & CO KG, MINDEN GERMANY 2/6-10/12,ETC - 483S
2013-741	01/30/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	JHP PHARMACEUTICALS LLC, ROCHESTER, MI - EIR, 483, CO RESP 3/12
2013-742	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	GUARDIAN DRUG CO, DAYTON, NJ - EIR, 483, CO RESP 3/12
2013-743	01/30/2013 02/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	NOVO NORDISK A/S, GENTOFTE, DENMARK 6/28-26/12; NOVO NORDISK A/S, HILLEROED, DENMARK 3/21/12; NOVO NORDISK A/S, KALUNDBORG, DENMARK 3/5-9/12 - 483S
2013-744	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	RTI BIOLOGICS, ALACHUA, FL - EIR, CORR 6.25/12-7/11/12
2013-745	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	GENZYME FLANDERS NV, GEEL, BELIGIUM 1/16/24/12; HOSPIRA COSTA RICA LTD, LA AURORA DE HEREDIA, COSTA RICA 4/16-19/12; BRISTOL-MYERS SQUIBB, ANAGNI, ITALY 3/5-8/12, ETC - 483S
2013-746	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	BECTON DICKINSON DE MEXICO, CUAUTITLAN IZCALLI, MEXICO 1/16-19/12; AKZO NOBEL CHEMICALS SA DE CV, LOS REYES LA PAZ EDO, MEXICO 3/26-30/12 - 483S
2013-747	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	SHIONGI & CO LTD, AMAGASAKI-SHI, JAPAN 2/10-15/12; TAKEDA PHARMACEUTICAL CO LTD, HIKARI, JAPAN 7/17-20/12 - 483S

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2013-748	01/30/2013 02/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	DEPUY (IRELAND) LOUGHBEG, RINGASKIDDY, IRELAND 1/23-26/12; JANSSEN BIOLOGICS (IRELAND) BARNAHELY, RINGASKIDDY, IRELAND 6/12-18/12 - 483S
2013-749	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	DR MALCOLM PAUL, NEWPORT BEACH, CA 6/14/12-7/17/12; DR RICHARD D'AMICO, ENGLEWOOD, NJ 10/11/12-11/12/12, ETC - EIR, 483, CO RESP
2013-750	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	ASTRAZENCA, MACCLESFIELD, CHESHIRE, UK 3/12-16/12; DEPUY INTERNATIONAL LTD, LEEDS, UK 2/13-16/12 - 483S
2013-751	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	HAMELN PHARMACEUTICALS GMBH, HAMELN, GERMANY - EIR, 483, CO RESP 6/4-14/12
2013-752	01/30/2013 02/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	NOVARTIS PHARMA BPO, HUNINGUE, FRANCE 1/23-31/12; SANOFI CHIMIE, PLOERMEL, FRANCE 3/26-30/12 - 483S
2013-753	01/30/2013 02/28/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	APP PHARMS, GRAND ISLAND, NY - EIR, 483, CORR 10/2- 19/12
2013-754	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	BOEHRINGER INGELHEIM RCV GMBH, VIENNA, AUSTRIA 3/15/23/12; DSM FINE CHEMICALS AUSTRIA GMBH NFG

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2013-755	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	POLYMED THERAPEUTICALS INC, ERLANG, CHINA 5/21-23/12; CHONGQING KANGLE PHARMACEUTICAL CO LTD, CHONGQING, CHINA 4/23-26/12 - 483S
2013-756	01/30/2013 02/28/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR 6/26/12-7/12/12; BIO LAB-ST JOSEPH CORP, BAYAMON, PR 4/17/12-5/9/12; ABBOTT DIAGNOSTICS INTERNATIONAL LTD, BARCELONETA, PR 1/18-12-3/12/12, ETC - 483S
2013-757	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	IMPLANT RESCOURCE INC, BURNSVILLE, MN 5/16-12-6/17/12; MEDTRONIC NEUROMODULATION, MINNEAPOLIS, MN 3/14/12-5/9/12; BOSTON SCIENTIFIC CRM CORP, SAINT PAUL, MN 3/19/12-4/16/12, ETC
2013-758	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	THOMPSON, RAY	GLAXOSMITHKLINE CONSUMER HEALTHCARE LP, CLIFTON, NJ 12/20/11 TO 1/9/12; AUSTARPHARMA LLC, EDISON, NJ 5/30/12-6/5/12; ACTAVIS ELIZABETH LLC, ELIZABETH, NJ 12/13/11 TO 1/13/12, ETC - 483S
2013-759	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	THOMPSON, RAY	NOVARTIS VACCINE & DIAGNOSTICS INC, EMERYVILLE, CA 3/20-30/12; IMMUNETECH INC, FOSTER CITY, CA 3/12-23/12; BIOGENEX LABORATORIES INC, FREMONT, CA 12/20/11 TO 1/6/12, ETC - 483S
2013-760	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMPSON, RAY	SANDOZ PRIVATE LTD (NOVARTIS), NAVI MUMBIA, INDIA 1/2-9/12; CADILA HEALTHCARE LTD, AHMEDABAD CITY, INDIA 2/13-23/12; CIPLALTD, BANGALORE, KARNATAKA, INDIA 6/21-28/12, ETC - 483S
2013-761	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	NOVARTIS PHARMA AG, BASEL, SWITZERLAND 7/19-26/12; CILAG AG, SCHAFFHAUSEN, SWITZERLAND 4/20-27/12; NOVARTIS PHARMA STEIN AG, STEIN, SWITZERLAND 6/11-22/12, ETC - 483S
2013-762	01/30/2013 02/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON, RAY	APOTEX FERMENTATION INC, WINNIPEG, CANADA 6/4-7/12; CONTRACT PHARMACEUTICALS LTD (CPL), MARKHAM, CANADA 1/31/12 TO 2/2/12; CARDIOMED SUPPLIES INC, LINDSAY, CANADA 2/20-23/12 - 483S
2013-763	01/30/2013	FDA/OF/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN	FCN 1206

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	02/28/2013		Keller and Heckman LLP	
2013-764	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, KENT, WA - EIR 2/12
2013-765	01/30/2013 02/28/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRENDA M GARTZ ELI LILLY & CO	BACHEM INC, TORRANCE, CA - EIR 1/20/12
2013-766	01/30/2013 02/28/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, ST LOUIS, MO - EIR 2/11
2013-767	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	CHRISTOPHER WEAVER WALL STREET JOURNAL	2008-1744, 2011-7185, 2012-3210, ETC
2013-768	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	CHRISTOPHER WEAVER WALL STREET JOURNAL	2008-3812, 2012-3360, 2012-3741
2013-769	01/30/2013 02/28/2013	FDA/OC/OES/DFOI/	BERNIE BURGESS BURGESS, BERNIE	RECS RE: FOI REQUEST
2013-770	01/30/2013 02/28/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	THOMPSON, RAY	ADVANCED ORTHOPRO INC, INDIANAPOLIS, IN 4/6-26/12; L PERRIGO CO, ALLEGAN, MI 4/17/12-5/8/12; ACUMEDIA MANUFACTURERS INC, LANSING, MI 12/19/11-1/9/12, ETC - 483S
2013-771	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Superfine Rheomics, Inc.	K062604
2013-772	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	OSCAR GOODMAN, NEVADA CANCER CENTER, LAS VEGAS, NV - EIR (6/25/2012 - 07/03/2012)
2013-773	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	MEDIVATION, SAN FRANCISCO, CA - EIR 06/08/12
2013-774	01/31/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Michael Feiler Quilling Selander Lownds Winslett & Moser	INVACARE - INSPECTION RECS, CORR, UNTITLED LETTER ETC
2013-775	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Linda Bowen SANOFI	GENENTECH, HILLSBORO, OR; GENENTECH, SAN FRANCISCO; GENENTECH, VACAVILLE, CA ETC - 483
2013-776	01/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Juan Herrera	AIDI BIOMEDICAL - MDR SINCE 01/01/2013

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	03/01/2013		AIDI Biomedical	
2013-777	01/31/2013 03/01/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Joshua A. Leach Baxter Healthcare Corp.	SYNOVIS DURA-GUARD - SAMPLE RESULTS
2013-778	01/31/2013 03/01/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	ANDREW ARMSTRONG, DUKE UNIVERSITY MEDICAL CENTER, DURHAM, NC - EIR (6/13/12)
2013-779	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Laura Hass Hass, Laura	ETHICON, ETHICON ENDO-SURGERY GASTRIC BYPASS SURGERY STAPLERS - COMPLAINTS, INVESTIGATIONS, REPORTS ETC
2013-780	01/31/2013 03/01/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Mahidhar Chinta MICRO LABS USA INC	NDA 203491
2013-781	01/31/2013 03/01/2013	FDA/OO/OFBA/OAGS/	Shadonna Messiah United Union Of Security Guards	HSH-QEC-12-D-00002
2013-782	01/31/2013 03/01/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jay Wrobel, Ph.D. Fox Chase Chemical Diversity Center	RILUZOLE - SUMMARIES OF IN VITRO AND ANIMAL SAFETY PHARMACOLOGY AND TOXICOLOGY STUDIES
2013-783	01/31/2013 03/01/2013	FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/	Scott Krygier BASF - The Chemical Company	FAP 2269
2013-784	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tomas Friend KIPA AB	AGA MEDICAL CORP - MATERIALS SUBMITTED FOR OCCLUDER OR OCCLUSION DEVICE (01/02/1996 - 01/02/2001)
2013-785	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Xiang Liu Blackrock	HILL-ROM, BATESVILLE, IN - 483 (09/01/2012 - 01/01/2013)
2013-786	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	LIFE EXTENSION - Alexandra Ajmo Ajmo, Alexandra	US PHARMA LAB INC, NORTH BRUNSWICK, NJ - EIR (01/01/2012 - 01/01/2013)

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2013-787	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tomas Friend KIPA AB	PMA P000039
2013-788	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cathy Shachaf Orlucent	K014018
2013-789	01/31/2013 03/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	RSA CORP, DANBURY, CT; ALLERQUEST LLC, PLAINVILLE, CT; PCI SYNTHESIS, NEWBURYPORT, MA, ETC - 483S 12/1-31/12
2013-790	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDA NEWS	GUY & O'NEILL INC, FREDONIA, WI; BRUNO INDEPENDENT LIVING AIDS INC, OCONOMOWOC, WI - 483S 12/1-31/12
2013-791	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDA NEWS	CUSTOM COMPOUNDING CENTERS, LOS ALAMITOS, CA; SCIENTIFIC PHARMACEUTICALS INC, POMONA, CA; BIOSEAL CORP. PLACENTIA, CA, ETC - 483S 12/1-31/12
2013-792	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDA NEWS	NESHER PHARMACEUTICALS (USA) LLC, BRIDGETON, MO; NESHER PHARMACEUTICALS (USA), LLC, SAINT LOUIS, MO; WEXFORD LABS INC, KIRKWOOD, MO - 483S 12/1-31/12
2013-793	01/31/2013 03/01/2013	ORA/ ORA/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDANEWS	ORION CORP, ESPOO, FINLAND - 483S 12/1-31/12
2013-794	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDANEWS	AMERICAN ORTHO-TECH (P) LTD, CHENNAI, TAMBARAM, INDIA; UNOMEDICAL LSDN BHD, SUNGAI PETANI, KEDAH, MALAYSIA; GARAVENTA (CANADA) LTD, ST SURREY, CANADA, ETC - 483S 12/1-31/12
2013-795	01/31/2013 03/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	BSP PHARMACEUTICALS SRL, LATINA SCALO, ITALY; FARMHISPANIA SA, MONTMELO, SPAIN; SICOR SRL, SANTHIA (VC), ITALY, ETC - 483S 12/1-31/12
2013-796	01/31/2013 03/01/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDA NEWS	PETNET SOLUTIONS INC, FORT LAUDERDALE, FL; CFS DENTAL INC, HIALEAH, FL; VYCOR MEDICAL INC, BOCA RATON, FL, ETC - 483S 12/1-31/12
2013-797	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDA NEWS	PFIZER INC, ROCHESTER, MI; EXCEL MEDICAL PRODUCTS INC, FENTON, MI - 483S 12/1-31/12
2013-798	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOHNATHAN RICKMAN FDA NEWS	BENCHMARK MEDICAL INC, SALT LAKE CITY, UT; WATSON LABORATORIES INC, SALT LKE CITY, UT; FRESENIUS MEDICAL CARE NORTH AMERICA, OGDEN, UT, ETC

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2013-799	01/31/2013 03/01/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	AMERICAN PHARMACEUTICALS & COSMETICS INC, FORT WORTH, TX; CYBERONICS INC, HOUSTON, TX; MEDRO SYSTEMS INC, MCKINNEY, TX, ETC - 483S 12/1-31/12
2013-800	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	JOHNATHAN RICKMAN FDA NEWS	PEMCO INC, INDEPENDENCE, OH; NORMAN NOBLE INC, HIGHLAND HEIGHTS, OH; HAVELS INC, CINCINATI, OH, ETC - 483S 12/1-31/12
2013-801	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	MEDFIL INC, GLENDALE HEIGHTS, IL; LATTICE INC, WHEATON, IL; DEL MEDICAL INC, ROSELE, IL - 483S 12/1-31/12
2013-802	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	JOHANTHAN RICKMAN FDANEWS	RX SOUTH LLC (DBA RX3 PHARMACY), CHESTER, VA; HEMAGEN DIAGNOSTICICS INC, COLUMBIA, MD; ACELL INC, COLUMBIA, MD - 483S 12/1-31/12 - 483S 12/1-31/12
2013-803	01/31/2013 03/01/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDANEWS	SUMMIT INDUSTRIES, MARRIETA, GA; HEAVENLY HARVEST INC, MOULTRIE, GA - 483S 12/1-31/12
2013-804	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDANEWS	BLOOD BANK COMPUTER SYSTEMS INC, AUBURN, WA; CARDINAL LHEAL 414 INC, SEATTLE, WA; MALONEY'S CUSTOM OCULAR PROSTHETICS, LAKE OSWEGO, OR, ETC - 483S 12/1-31/12
2013-805	01/31/2013 03/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LEO STERNLICHT RIDGEBACK CAPITAL MANAGEMENT LLC	SALIX PHARMACEUTICALS - RELISTOR (METHYLNALTREXONE BROMIDE) CO RESP
2013-806	01/31/2013 03/01/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	MASSEY, GEORGE	INDIVIDUAL RECS
2013-807	01/31/2013 03/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KYRIAKIDIS, JOANNA	LTR TO KAREN TANNERT, RPH TX DEPT OF STATE HEALTH SERVICES 5/4/05
2013-808	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDA NEWS	NU WORLD CORP, CARTERET, NJ; OHM LABORATORIES INC, NEW BRUNSWICK, NJ; CATALENT PHARMA SOLUTIONS LLC, SOMERSET, NJ - 483 12/12
2013-809	01/31/2013 03/01/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	BD CARIBE LTD, CAYEY, PR; KNOLL LLC, JAYUYA, PR - 483 12/12
2013-810	01/31/2013 03/01/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDANEWS	INTERSECT ENT INC, PALO ALTO, CA; AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA; NATUREX INC, SHINGLE SPRINGS, CA - 483 12/12
2013-811	01/31/2013 03/01/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDA NEWS	B BRAUN MEDICAL INC, ALLENTOWN, PA - 483 12/12

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2013-812	01/31/2013 03/01/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDANEWS	ASCENT PHARMACEUTICALS INC, CENTRAL ISLIP, NY; HI TECH PHARMACAL CO INC, AMITYVILLE, NY; NOVARTIS PHARMACEUTICALS CORP, SUFFERN, NY - 483 12/12
2013-813	01/31/2013 03/01/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDANEWS	CRYOSURGERY INC, NASHVILLE, TN; AXIS HEALTH CARE LLC, MONTGOMERY, AL - 483 12/12
2013-814	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTOPHER B. SPUCHES, Esq. EHRENSTEIN CHARBONNEAU ET AL	CANNULATED BONE SCREW K061620; BONE FIXATION DEVICE K071035; PROFILE PLATES SCREWS & WASHERS K110086
2013-815	01/31/2013 03/01/2013	FDA/OF/CFSAN/OCD/EOS/	ROBERT A. DeCAMP DERINGER LOGISTICS CONSULTING GROUP	AN DERINGER INC - LTR SHOWING CO AS AN AGENT OF THE US
2013-816	01/31/2013 03/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	ACIST ANGIOGRAPHIC CONTRAST MGMT INJECTORSYS MODEL CMS2000 k991103; ACIST ANGIOGRAPHIC INJECTION SYS, MODEL R2000 CMS (K010390); ACIST ANGIOGRAPHIC CONTRAST MGMT SYS (K984231)
2013-817	01/31/2013 03/01/2013	FDA/OC/OES/DFOI/	ROSS D. PLONT GRUEL MILLS NIMS & PYLMAN LLP	CARDINAL HEALTH EXCHANGE TRANSFUSION TRAY 6/13/07
2013-818	01/31/2013 03/01/2013	FDA/OC/OES/DFOI/	ROSS D. PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE PHARMASEAL EXCHANGE TRANSFUSION TRAY 2/20/02
2013-819	01/31/2013 03/01/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK SCHOOF PRO PUBLICA	RESPONSE LTR FROM FDA TO CETERO RESEARCH 7/26/11
2013-820	01/31/2013 03/01/2013	ORA/OCI/ ORA/OCI/	COLOSI, JOSEPH A	INDIVIDUAL RECS
2013-821	02/01/2013 03/04/2013	CVM/OCD/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Ryan T. Kearney COZEN O'CONNOR	HARTZ CHICKEN CHEWS, HARTZ OINKIE PIG SKIN WRAPPED WITH CHICKEN - INVESTIGATION, INSPECTIONS, TESTING, ETC
2013-822	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bobbie Sanderson Sanderson, Bobbie	FORTEO - NUMBER OF MEDWATCH RPTS FOR OSTEOSARCOMA, BONE CANCER

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2013-823	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	KARIM FIZAZI, INSTITUTE GUSTAVE-ROUSSY, VILLEJUIF, FRANCE - EIR (07/30/2012 - 08/03/2012)
2013-824	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	WOLFGANG LOIDL, LINZ UROLOGIE ABTEILUNG, LINS, AUSTRIA - EIR (08/2012)
2013-825	02/01/2013 03/04/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OF/CFSAN/OCD/EOS/	Becky Cooseman Brown & Crouppen, PC	SAMPLE 661933 - ALL RECS
2013-826	02/01/2013 03/04/2013	FDA/OC/OES/DFOI/	MINTZ GROUP	SUREPATH FLUID COLLECTION VIAL - FOI REQUESTS
2013-827	02/01/2013 03/04/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/ OM/OMP/DODM/	CHARLOTTE VALLAEYS CORNUCOPIA INSTITUTE	DKT 2008P-0347
2013-828	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	REBECCA FIELD EMERSON MITTS LAW LLC	PHARMEDIUM SERVICES LLC - WARNING LTRS, APRVL RECS, INSPS, ETC 1/07 TO PRESENT
2013-829	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	REBECCA FIELD EMERSON MITTS LAW LLC	CENTRAL ADMIXTURE PHARMACY SERVICES INC, B BRAUN MEDICAL INC - WARNING LTRS, APRVL RECS, INSPS, ETC 1/07 TO PRESENT
2013-830	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RAVI DESHPANDE ACINO PRODUCTS LLC	JANSSEN PHARMA - TERAZOL 3 (TERCONAZOLE) VAGINAL SUPPOSITORY NDA 19-641; PERRIGO NEW YORK - TERCONAZOLE VAGINAL SUPPOSITORY ANDA 77-149 SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-831	02/01/2013 03/04/2013	FDA/OMPT/CTP/OD/	FOI Services, Inc.	NAMES OF ESTABLISHMENTS ENGAGED IN THE MANUFACTURE, PREPARATION, COMPOUNDING OF TOBACCO PRODS
2013-832	02/01/2013 03/04/2013	FDA/OF/CFSAN/OCD/EOS/	DAVID C STEINBERG STEINBERG & ASSOCIATES INC	HAIR STRAIGHTENER COSMETICS - CAERS 2000 TO PRESENT
2013-833	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	CURTIN, DENNIS D	OCTAPHARMA AB, STOCKHOLM, SWEDEN - 483 1/11
2013-834	02/01/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Empire State Consumer Project, Inc	DKT 2012P-0566
2013-835	02/01/2013 03/04/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CONKLIN COMPANY INC - EIR, 483, CO RESP 10/12
2013-836	02/01/2013 03/04/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Doe J	INDIVIDUAL RECS
2013-837	02/01/2013 03/04/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS-	Lorraine Shelton Exova Inc.	AAI PHARMA SERVICES, EDISON, NJ - EIR 3/15/12; IRVINE PHARM SERVICES, IRVINE, CA - EIR 11/24/09, 4/2/12; NORTH AMERICAN SCIENCE ASSOC INC, IRVINE, CA - EIR 10/14/11; NORTH AMERICAN SCIENCE ASSOC, NORTHWOOD, OH - EIR 12/9/11

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		DO/LOS-CB/		
2013-838	02/01/2013 03/04/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT FDA-1975-N-0355
2013-839	02/01/2013 03/04/2013	OC/OM/OMP/DDM/	ANGELIA SLAYTON INC RESEARCH CONSULTING & SUBMISSIONS	OTC VOLS. 160414, 160397
2013-840	02/03/2013 03/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Mara Goldstein Cantor Fitzgerald/Mara Goldstein	CELLDEX THERAPEUTICS CDX-011 - MINUTES FROM END OF PHASE 2 MTGS
2013-841	02/03/2013 03/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Christopher Weaver THE WALL STREET JOURNAL	BARDOXOLONE METHYL - IND SAFETY AND EFFECTIVENESS RECS
2013-842	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS (01/012013-01/31/2013)
2013-843	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG (12/31/2012 - 2/1/2013)
2013-844	02/03/2013 03/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 270905, 271928, 272975 ETC
2013-845	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JEROME LEW MEDTRONIC (INFUSE BMP)	OFF LABEL USE OF MEDTRONIC INFUSE BMP IN THE CERVICAL SPINE AND IMPROPER SUBMISSION OF HUMAN SUBJECTS INTO CLINICAL TRIALS OR STUDIES - INVESTIGATION RECS
2013-846	02/03/2013 03/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Andrew Ellis PRIVATE CITIZEN	VIDEX, VIDEX EC -REPORTS RE PORTAL HYPERTENTION
2013-847	02/03/2013 03/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Kelli Chan Kelli Chan	LEVAQUIN, CIPRO, AVELOX, ETC - AERS
2013-848	02/03/2013	FDA/OGROP/ORA/CE-FO/PHI-	Tonya Bechtel	SHARP, ALLENTOWN, PA - EIR (APRIL 2011)

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	03/04/2013	DO/PHI-CB/	Tarsa Therapeutics, Inc.	
2013-849	02/03/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kimberly Clarke Dr.Emma's Corporation	HCG INJECTIONS - AERS
2013-850	02/03/2013 03/04/2013	OM/OMP/DODM/	Chris Lahiff Chris Lahiff c/o McDermott Will & Emery	MEMORANDUM TO THE RECORD 2012 REFERENCED IN STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION
2013-851	02/03/2013 03/04/2013	ORA/ ORA/	Christopher Weaver THE WALL STREET JOURNAL	SAMPLE RESULTS FROM INDUSTRY CODES 56, 57, 60-66
2013-852	02/03/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mara Goldstein Cantor Fitzgerald/Mara Goldstein	ADCETRIS - AERS
2013-853	02/03/2013 03/04/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	HUMATE-P - ORPHAN DRUG DESIGNATION
2013-854	02/03/2013 03/04/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	Michael Atkins Atkins Intellectual Property, PLLC	ZAO GRUPPA PEDPRIYATIJ OST, ZAO OST AQUA, LTD AQUA LIFE - IMPORTATION, DISTRIBUTION, PACKING, SALE ETC
2013-855	02/03/2013 03/04/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	Michael G. Atkins Atkins Intellectual Property, PLLC	DUCHESSE, DIOWEC DUSHESSE, EXTRA-CIDER ETC - IMPORTATION, DISTRIBUTION, PACKING ETC
2013-856	02/03/2013 03/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Letter Odom & Des Roches, LLP	NDA 76436, 76905, 76905 ETC - TENTATIVE APPROVAL LETTERS
2013-857	02/03/2013 03/04/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Mark W. Sherman LRP PUBLICATIONS	JUDGE ROTENBERG CENTER, CANTON, MA - CORR 5/23/11, 6/29/12
2013-858	02/03/2013 03/04/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Nanci Martinez for Martinez Food Company Martinez Food Company	MARTINEZ FOOD CO, ELGIN, TX - INSPECTION RECS (01/01/2013 - 01/31/2013)
2013-859	02/03/2013	ORA/OCI/	Christopher Weaver	CANADA DRUGS, KRIS THORKELSON - RELEASABLE RECS

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	03/04/2013	ORA/OCI/	THE WALL STREET JOURNAL	IN CRIMINAL CASE
2013-860	02/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Ole Pedersen	ANDA 077850
	03/04/2013	FDA/OMPT/CDER/GRP/DIDP/	Alkalon AS	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-861	02/03/2013	FDA/OF/CFSAN/OCD/EOS/	Janet Horn	LIST OF ALL FDA REGISTERED DRUG COMAPNIES, COSMETIC/PERSONAL CARE COMPANIES
	03/04/2013	FDA/OMPT/CDER/GRP/DIDP/	BD Diagnostic Systems / Janet Horn	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-862	02/03/2013	OC/OOPD/	Rachel Johnson	WILATE - ORPHAN DRUG APPLICATION
	03/04/2013	FDA/OMPT/OSMP/OOPD/	FOI Services, Inc.	
2013-863	02/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Teresa Porter	VIMPAT - AERS
	03/04/2013	FDA/OMPT/CDER/GRP/DIDP/	not applicable	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-864	02/03/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Anthony Lenza, Esq.	HILL-ROM CLINITRON CII RECALL Z-0989-03 - DOCS, LETTERS, RPTS
	03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amabile & Erman, P.C.	
		FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/		
2013-865	02/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Attorney Gary Liquori	METHADONE PUBLIC HEALTH ADVISORY 11/27/2006 (CERTIFIED)
	03/04/2013	FDA/OMPT/CDER/GRP/DIDP/	Powers & Liquori, Attys at Law	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-866	02/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Shelburne	K083458
	03/04/2013	FDA/OC/OES/DFOI/	Ellipse Technologies Inc	
2013-867	02/03/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	David Kim	NOVO NORDISK, DENMARK - WARNING LETTER, 483 (01/01/2012 - 12/31/2012)
	03/04/2013	FDA/OMPT/CDER/GRP/DIDP/	David Kim	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-868	02/03/2013	FDA/OC/OES/DFOI/	Amy Kincanon	2011-3365

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	03/04/2013		LexisNexis CourtLink Document Retrieval	
2013-869	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2009-6614
2013-870	02/03/2013 03/04/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2010-7304
2013-871	02/03/2013 03/04/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	B Burgess BURGESS, BERNIE	FACTS 808885 - 482
2013-872	02/03/2013 03/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Kristina Hahn-Major B. Braun Medical Inc.	ANDA 200222
2013-873	02/03/2013 03/04/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	TEXAS BIOMEDICAL RESEARCH, SAN ANTONIO, TX - 483 (09/01/2012 - 10/31/2012)
2013-874	02/03/2013 03/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	PHARMANET, PRINCETON, NJ - 483 (09/01/2012 - 10/31/2012)
2013-875	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard A Conlen MD R&G Medical and Development Corp.	K080464
2013-876	02/03/2013 03/04/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	BAXTER HEALTHCARE IV DIVISION, MARION, NC - 483, SAMPLE RESULTS
2013-877	02/03/2013 03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Greg Nagle Aurora Photonics Inc.	K011244
2013-878	02/04/2013 03/05/2013	FDA/OF/CFSAN/OCD/EOS/	TIMOTHY J REULAND SPEERS REULAND & CIBULSKIS PC	CANTALOUPE DNA FINGERPRINT RECS
2013-879	02/04/2013 03/05/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	LAURA HOBBS LEXISNEXIS COURTLINK INC	AMOUNT OF 14-HYDROXYCODEINONE PREMITTED IN OXYMORPHONE HCL ATIVE PHARMACEUTICAL INGREDIENT (API) - RECS
2013-880	02/04/2013 03/05/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	PATRICK E MA OD MD UNIV OF BRITISH COLUMBIA	PATRICK MA MD - UNTITLED LTR, EIR, 483 5/22/00

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-881	02/04/2013 03/05/2013	OC/COS/OES/ OC/COS/OES/ FDA/OC/OES/DFOI/ ORA/OCI/ ORA/OCI/	Doe J	INDIVIDUAL RECS
2013-882	02/04/2013 03/05/2013	FDA/OC/OES/DFOI/	KELLY A FITZPATRICK LANIER LAW FIRM	2012-8844 - MINOR DELETIONS
2013-883	02/04/2013 03/05/2013	FDA/OC/OES/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	CARDINAL HEALTH - EXCHANGE TRANSFUSION FORM FDA 3500A, RPTS, MEMOS, ETC
2013-884	02/04/2013 03/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLAS, BRIAN	ISRS 3177015-7, 3412365-8, 3208564-0, ETC
2013-885	02/04/2013 03/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AZIM CHOWDHURY Keller and Heckman LLP	NICORETTE NDA 18-612/S022 - FIVE USAGES STUDIES, RVW MEMOS
2013-886	02/04/2013 03/05/2013	FDA/OF/CFSAN/OCD/EOS/	ANNA FLOOD Keller and Heckman LLP	FCN 1233
2013-887	02/04/2013 03/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS - VAERS
2013-888	02/04/2013 03/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS - VAERS
2013-889	02/04/2013 03/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTINA CIAMPOLILLO ESQ CONWAY HOMER & CHIN- CAPLAN PC	MERCK & CO INC - GARDASIL POST-MARKETING REQUIREMENTS, RPTS, STUDIES, ETC
2013-890	02/04/2013 03/05/2013	FDA/OF/CFSAN/OCD/EOS/	MITCHELL A CHEESEMAN STEPTOE & JOHNSON	HERCULES INC - FAP 0B2442
2013-891	02/04/2013 03/05/2013	FDA/OF/CFSAN/OCD/EOS/	ALBA 89560-012, DENNIS	ASPARTAME - RECS, CAERS

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2013-892	02/04/2013 03/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD MOSS MOSS MEDICAL PRODUCTS INC	K910912, K890871
2013-893	02/04/2013 03/05/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	COLEEN KLASMEIER SIDLEY AUSTIN LLP	LIFECCELL CORP - EIRS, 483S, COR RESP, ETC 5/6/11 TO 1/30/13
2013-894	02/04/2013 03/05/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Doe J	MEDTRONIC - SYNCHROMED II BACLOFEN INFUSION PUMP RECALL RECS
2013-895	02/04/2013 03/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLAS, BRIAN	ABBOTT LABS - BIAVIN (CLARITHROMYCIN) CHANGES BEING EFFECTED (CBE), POST-MARKETING RPTS, DEAR DOCTOR LTRS
2013-896	02/04/2013 03/07/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JANE CARROLL COMMUNITY TISSUE SERVICES	MUSCULOSKELETAL TRANSPLANT FOUNDATION - EIR MOST RECENT
2013-897	02/04/2013 03/05/2013	FDA/OF/CFSAN/OCD/EOS/	TAMI DALBERG INDENA USA INC	FLAVEX NATUREXTRAKTE GMBH, REHLINGEN, GERMANY - EIR 4/19-20/12
2013-898	02/04/2013 03/05/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, JACKSONVILLE, FL - EIR 3/11
2013-899	02/04/2013 03/05/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, DALLAS, TX - EIR 3/11
2013-900	02/04/2013 03/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BRENDA M GARTZ ELI LILLY & CO	PETNET SOLUTIONS, ATLANTA, GA - EIR 2/11
2013-901	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Adam Cole Excel Medical Products, Inc.	K884327
2013-902	02/05/2013 03/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	An Wending Hisun Pharmaceuticals USA Inc.	TYPE II DRUG MASTER FILES SUBMITTED TO FDA (2007-2012)
2013-903	02/05/2013 03/06/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OF/CFSAN/OCD/EOS/	Michelle Celarier Michelle Celarier, New York Post	HERBALIFE FORMULA ONE, HERBALIFE PERSONALIZED PROTEIN POWDER - COMPLAINTS, INVESTIGATIONS (01/01/2005 - 02/04/2013)

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2013-904	02/05/2013 03/06/2013	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Peter Nesbitt Quasar Bio-Tech Inc., aka Silver Bay LLC	QUASAR BIO-TECH, SILVER BAY LLC, SARASOTA, FL - REPORTS, LETTERS, EMAIL ETC
2013-905	02/05/2013 03/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lakshmi Raghavan DermPathe Pharmaceuticals	ZOVIRAX OINTMENT FORMULATION INFORMATION
2013-906	02/05/2013 03/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EMCURE PHARMACEUTICALS, PUNE, INDIA - EIR (JUNE 2011)
2013-907	02/05/2013 03/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	FERRIC CITRATE - LIST OF NDA, ANDA
2013-908	02/05/2013 03/06/2013	FDA/OC/OES/DFOI/	Steven F. Napolitano Skadden, Arps, Slate, Meagher & Flom LLP	FOIA REQUESTS RE ZOLOFT
2013-909	02/05/2013 03/06/2013	CVM/OCD/ FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/OR/SW-FO/DAL-DO/DAL-CB/	Marc Selinger EXAMINER.COM	COMPLAINT 130061
2013-910	02/05/2013 03/06/2013	FDA/OGROP/OR/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melissa Henderson Melissa Henderson	DANIEL H PRESENT, NEW YORK, NY - MEMO TO FILE
2013-911	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/OR/SW-FO/DAL-DO/DAL-CB/	james mcgovern MCGOVERN, JAMES J	DR J TENNAT - FOLLOW UP OR CLOSE OUT TO WARNING LETTER DATED 2/15/05
2013-912	02/05/2013 03/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	PULMOZYME BLA 103532 APRVL, LBLG, PHARMACOLOGY RVW, CHEMISTY RVW

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-913	02/05/2013 03/06/2013	ORA/ ORA/	FAVID BLOCH MEDTRONIC	ST JUDE MEDICAL, SYLMAR, CA - CO RESP 1/10/13
2013-914	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD MOSS MOSS MEDICAL PRODUCTS INC	BARD MOSS GASTROSTOMY TUBE K890871
2013-915	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD MOSS MOSS MEDICAL PRODUCTS INC	BIOSEARCH MEDICAL PRODUCTS INC K935045; K923474
2013-916	02/05/2013 03/06/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	HU, QIYONG	MINDRAY MEDICAL INT'L, NY; CHINA - INSP LAST 5 YRS, WARNING LTRS, CO RESP
2013-917	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY HEMPEL VIGIL LAW FRIM	OLYMPUS LF-GP FIBEROPTIC INTUBATION SCOPE - CORR 1/08 TO PRESENT
2013-918	02/05/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	KELLY HEMPEL VIGIL LAW FRIM	INDIVIDUAL RECS
2013-919	02/05/2013 03/06/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	SINEAD O'DONOGHUE GLOOR LAW GROUP LLC	CHARGE BEVERAGES CORP - LIQUID CHARGE; UNITED BRANDS COMPANY INC - JOOSE; PHUSION PROJECTS LLC - FOUR DOCS
2013-920	02/05/2013 03/06/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE, HYDROXYCUT, SMARTBURN, ETC - AER SINCE 10/31/12
2013-921	02/05/2013 03/06/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JENESSA G.B. COCCARO KERCSMAR & FELTUS PLLC	GARPARI NUTRITION INC - HALODROL LIQUIGELS & HALODROL MT, NOVEDEX XT; ORASTAN A - AER, CMLPTS 1/05 TO 12/11
2013-922	02/05/2013 03/06/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-2751, 2012-8672
2013-923	02/05/2013 03/06/2013	CVM/OCD/ OC/COS/OES/ OC/COS/OES/ OC/OCC/ OM/OMP/DODM/	ELISABETH HOLMES CENTER FOR FOOD SAFETY	RACTOPAMINE - AER
2013-924	02/05/2013 03/06/2013	FDA/OF/CFSAN/OCD/EOS/	FOI Services, Inc.	CFR 21, FOOTNOTE 4, PAGE 53

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2013-925	02/05/2013 03/06/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	KEVIN NOYES AMERICAN DONOR SERVICES	NEW LIFE GENERATION, INDIANAPOLIS, IN - EIR, 483, WARNING LTRS, CO RESP
2013-926	02/05/2013 04/08/2013	FDA/OC/OES/DFOI/	ALISON YOUNG USA TODAY	DIETARY SUPPLEMENT - 483 2009 TO PRESENT
2013-927	02/05/2013 03/06/2013	FDA/OMPT/CDRH/OCER/DFOI/OC/OCC/ FDA/OMPT/CDRH/OCER/DFOI/OC/OCC/	ANDRREW KINDER MINTZ GROUP	SURE PATH FLUID COLLECTION VIAL - TESTING USE 1/05 TO PRESENT
2013-928	02/06/2013 03/07/2013	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-D-0045
2013-929	02/06/2013 03/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Phil Sanderson NIH/NCATS	PRAZQUANTEL - SBA
2013-930	02/06/2013 03/07/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Taraneh Norouzi National Institutes of Health (NIH)	MAYO CLINIC NUCLEAR MEDICINE, DEPARTMENT OF RADIOLOGY, MINNESOTA - 483 (01/01/2010 - 01/31/2013)
2013-931	02/06/2013 03/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RECORD 1, 2, 3, 4 TRIALS - INSPECTIONS, AUDITS, INVESTIGATIONS BY OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
2013-932	02/06/2013 03/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RE-LY, RECORD 1, 2, 3, 4 TRIALS - INFORMED CONSENT FORMS
2013-933	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Daniel Burnett Theranova, LLC	K052025, K061333, K101847
2013-934	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nisha Arora ARCIM Advisors LLC	K062915, K002233
2013-935	02/06/2013 03/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Marielena Groeger PROPUBLICA	ORANGE BOOK - DATE FILES (01/01/1980 - 12/31/2012)
2013-936	02/06/2013	FDA/OMPT/CTP/OD/	Rachel Johnson	MANUFACTURERS, IMPORTERS OF TOBACCO PRODUCTS

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	03/07/2013	OC/OM/OFM/ FDA/OC/OES/DFOI/	FOI Services, Inc.	ASSESSED USER FEES (10/01/2012 TO PRESENT)
2013-937	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K073656
2013-938	02/06/2013 03/07/2013	FDA/OMPT/CTP/OD/ OC/OM/OFM/	Rachel Johnson FOI Services, Inc.	MANUFACTURERS, IMPORTERS OF TOBACCO PRODUCTS FOR WHICH USER FEE WAS RECEIVED (10/01/2012 TO PRESENT)
2013-939	02/06/2013 03/07/2013	FDA/OGROP/ORANE-FO/NWE- DO/NWE-CB/	Simon Fairbrass HEALTHCOR MANAGEMENT LP	LONZA BIOLOGICS, HOPKINTON, MA - WARNING LETTER, 483, CORR ETC
2013-940	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carrie Engleman SRI INTERNATIONAL	K081754 - DE NOVO PETITION
2013-941	02/06/2013 03/07/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	Leslie Patton BLOOMBERG NEWS	MCDONALDS - NON-EMERGENCY FOOD PROBLEM REPORTS
2013-942	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Diane Sudduth Biovance	K102478
2013-943	02/06/2013 03/07/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	Leslie Patton BLOOMBERG NEWS	YUM! BRAND RESTAURANTS - NON-EMERGENCY FOOD PROBLEMS
2013-944	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125156 S0076
2013-945	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112342
2013-946	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K032734
2013-947	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Esther Lee Horizon NJ Health	OXYTROL FOR WOMEN - APPROVAL RECS
2013-948	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K061848
2013-949	02/06/2013	FDA/OMPT/CDER/GRP/DIDP/	Tai-Li Chang, MD	COMPOUNDS CONTAINING FERRIC CITRATE, FERRIC

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	03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Venrock Associates	AMMONIUM CITRATE - REGULATORY DECISIONS AND ACTIONS, APPROVALS, GUIDANCE ETC
2013-950	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Aleksandr Rabodzey PFM (Attn: Alex Rabodzey)	PFIZER LYRICA STUDY - ENDPOINT ON PLACEBO
2013-951	02/06/2013 03/07/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/ORO/DIOP/	Mary Gustafson PPTA	IMPORT ALERT 57-01 BLOOD AND BLOOD COMPONENTS INCLUDING HUMAN PLASMA SERUM
2013-952	02/06/2013 03/07/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA LOG 01/28/2013 TO 02/01/2013
2013-953	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/COS/OL/ FDA/OC/OES/DFOI/ OC/OL/	CAROLLO, RUSSELL	VERISANTE AURA - RECS
2013-954	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	W E CHALKLEY THOMSON REUTERS	APTALIS PHARMA US - URSO 250 (URSODIOL) NDA 20-675 APRVL RECS
2013-955	02/06/2013 03/07/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Sarah Nugent BioSphere Medical, Inc.	BIOSPHERE MEDICAL, ROCKLAND, MA - EIR JUNE 2011
2013-956	02/06/2013 03/07/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KATHY NGUYEN ZONARE MEDICAL SYSTEMS INC	EVOLVE MANUFACTURING TECHNOLOGIES INC, MOUNTAIN VIEW, CA - EIR
2013-957	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM PHARMACEUTICALS INC - PRADAXA (DABIGATRAN ETESILATE MESYLATE) ANNUAL AND FINAL RPT
2013-958	02/06/2013 03/07/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	DARCI TEOBALDI HOGAN LOVELLS LLP	ADVANCED BIONICS CORP, SYLMAR, CA - 483 9/15/04, WARNING LTR 2/1/05, RECALL RECS, ETC

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2013-959	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RE-LY TRIAL - INSPECTION RECS BY DSI
2013-960	02/06/2013 03/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARKER GROUP INC	INDIVIDUAL RECS - VAERS
2013-961	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Crewdson PROJECT ON GOVERNMENT OVERSIGHT	RE-LY TRIAL - INSPECTIONS, INFORMED CONSENT, PRINCIPAL INVESTIGATOR CONTACT INFORMATION
2013-962	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CALLE M MENDENHALL FREESE & GOSS, PLLC	ACTOS (PIOGLITAZONE) NDA 21-073 - AERS, CORR, WARNING LTRS, ETC
2013-963	02/06/2013 03/07/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	GRAHAM J GILBERT SMITH HARTVIGSEN PLLC	RANGEN INC - CMLPTS, CORR, WARRANTS, ETC
2013-964	02/06/2013 03/07/2013	ORA/ ORA/ ORA/ORO/DFS/ ORA/ORO/DFS/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	TONY COVENY SIMON & LUKE LLP	CRIMSON CLOVER SPROUTS SEEDS - E COLI OUTBREAK IN AR, KS, IA, MO, WI 12/25/11 TO 1/15/12 RECS
2013-965	02/06/2013 03/07/2013	FDA/OO/OHR/	HENSON SR., J. DONALD	JOB DESCRIPTION FOR CDRH SENIOR RVW INDIVIDUAL OF P980022/S010,S011,S015; JOB DESCRIPTION FOR FDA OFFICE OF COMMISSIONER OMBUDSMAN, ETC
2013-966	02/06/2013 03/07/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	COLLEEN BOSWELL BIOLASE TECHNOLOGY INC	BIOLASE TECHNOLOGY INC, IRVINE, CA - EIR 8/2-4/11
2013-967	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	COLLEEN BOSWELL BIOLASE TECHNOLOGY INC	BIOLASE TECHNOLOGY INC - LASER PROD RPTS, ANNUAL RPTS ON RADIATION SAFETY TESTING OF LASER PRODS, ETC
2013-968	02/06/2013 03/07/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	FOI REQUESTS SUBMITTED FOR FY2008 TO FY2012

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2013-969	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RICHARD HAY RICHARD HAY LAW OFC	METFORMIN - AERS 2000 TO 2013
2013-970	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	SONG-SIK CHOI SHINHWAELECTRON CO LTD	TANDA SKINCARE SYS K080591; TANDA MAX OTC SYS K110735; ME K121598
2013-971	02/06/2013 03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	EPPERSON, FRANK	DENTAL SYRINGE - SAFETY FEATURES RECS
2013-972	02/06/2013 03/07/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC & FOREIGN INSPS 12/1-31/12
2013-973	02/06/2013 03/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY ANDERSON SHIRE PHARMACEUTICALS INC	NOVARTIS PHARMACEUTICALS CORP - NDA 21-882/S015 SBA
2013-974	02/06/2013 03/07/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS Consulting Group, LLC	NX GENERATION LTD, HAUPPAUGE, NY - 483 7/18,23,25/12
2013-975	02/06/2013 03/07/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	MARK C STANZIANO CHANFRAU & CHANFRAU	WHITNEY LABS, ORMOND BEACH, FL - EIRS 6/09 TO 6/11
2013-976	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121846
2013-977	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K851935 - SUMMARY
2013-978	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K914269 - SUMMARY
2013-979	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K915672 - SUMMARY
2013-980	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Rezach MEDTRONIC	K801080 - SUMMARY
2013-981	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Barclay Kime Genentech, Inc.	NDA 021436 S027 SBA

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2013-982	02/07/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2013-983	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Orsan Medical Technologies Osraen Medical Technologies	K981846, K962928, K103206
2013-984	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina M. Babos IPD Analytics, LLC	FERRIC CITRATE - APPROVED LABELING, SUMMARY REVIEW
2013-985	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sanja Ilic sanja ilic	MEDWATCH TPA2009A02453
2013-986	02/07/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	RHOGAM - RECALL RECS
2013-987	02/07/2013 03/08/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORAP/PA-FO/SEA- DO/SEA-CB/	Lytton Smith KARR TUTTLE CAMPBELL LAW OFFICES	TATTOO INK - SKIN INFECTIONS IN WASHINGTON STATE
2013-988	02/07/2013 03/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gyasi Bourne LightIntegra Technology Inc.	BK080014, BK070004, BK050034
2013-989	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Barclay Kime Genentech, Inc.	NDA 021444 S08 SBA
2013-990	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122027
2013-991	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111374
2013-992	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113059
2013-993	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122690
2013-994	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gabe Johnson Keyence Corporation	LASERS - PRODUCT REPORTS

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2013-995	02/07/2013 03/08/2013	FDA/OF/CFSAN/OCD/EOS/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ROQUETTE FRERES SA, LESTREM, FRANCE - 483 2012
2013-996	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Nostrum Laboratories, Inc. NOSTRUM LABORATORIES INC	CARAFATE SUSPENSION - CMC, CLINICAL STUDIES
2013-997	02/07/2013 03/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Gyasi Bourne LightIntegra Technology Inc.	BK110066
2013-998	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-9039 REQUEST LETTER
2013-999	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8808
2013-1000	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8783 - REQUEST LETTER
2013-1001	02/07/2013 03/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8747 REQUEST LETTER
2013-1002	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8816 REQUEST LETTER
2013-1003	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8772 - REQUEST LETTER
2013-1004	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8705 REQUEST LETTER
2013-1005	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8541 REQUEST LETTER
2013-1006	02/07/2013 03/08/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/ OC/COS/OL/ OM/OMP/DODM/ OC/OL/	Megan Pickel Beveridge & Diamond, PC	BIOTECH, BIENGINEERED, GENETICALLY MODIFIED FOOD LABELING - MEMOS, MINUTES, NOTES ETC LAST TWO YEARS
2013-1007	02/07/2013 03/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John M. Nardo MD John M. Nardo MD	NDA 019839

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2013-1008	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Plank Allergan, Inc.	CONJUNCTIN - NDA RECS
2013-1009	02/07/2013 03/08/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, NEW RICHLAND, MN - EIR, 10/24/12
2013-1010	02/07/2013 03/08/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, HEREFORD, TX - EIR 7/17/12
2013-1011	02/07/2013 03/08/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, CASA GRANDE, AZ - EIR 8/1/12
2013-1012	02/07/2013 03/08/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, STOCKTON, CA - EIR 8/6/12
2013-1013	02/07/2013 03/08/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, LITTLE CHUTE, WI - EIR 9/11/12
2013-1014	02/07/2013 03/08/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, LECOMPTE, LA - EIR 9/12/12
2013-1015	02/07/2013 03/08/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, SIOUX CITY, IA - EIR 9/26/12
2013-1016	02/07/2013 03/08/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL INC, BATAVIA, NY - EIR 7/10/12
2013-1017	02/07/2013 03/08/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	SUE CARLSON CARGILL ANIMAL NUTRITION	CARGILL ANIMAL NUTRITION, GIDDINGS, TX - EIR 6/6/12
2013-1018	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANOSHIMA, MD HOSPITAL FOR SICK CHILDREN	COPAXONE (GLATIRAMER ACETATE) - ISRS 6833424, 7246939, 7530249
2013-1019	02/07/2013 03/08/2013	ORA/OCI/ ORA/OCI/ OC/OM/OFM/	CHRIS CANTERGIANI SCRIPPS HOWARD NEWS SERVICE	STOLEN AGENCY ITEMS 2007 TO 2012
2013-1020	02/07/2013	FDA/OGROP/ORA/CE-FO/CHI-	GREGORY A. BEDELL	EVANGERS DOG & CAT FOOD CO - WARNING LTR

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	04/15/2013	DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	KNABE KRONING ET AL	QUESTIONS
2013-1021	02/07/2013 03/08/2013	FDA/OF/CFSAN/OCD/EOS/	ELOIT HARRISON LEWIS & HARRISON	FCN 567
2013-1022	02/07/2013 03/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	TIFFANY K. HANNUS LOMMEN ABDO COLE KING STAGEBERG PA	INDIVIDUAL RECS
2013-1023	02/07/2013 03/08/2013	FDA/OC/OES/DFOI/	Doe J	NATURALYTE, GRANUFLO - AERS
2013-1024	02/07/2013 03/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEX VEIZIS FDALIVE.COM	IMPACT OF APRVD DRUG ON CHRONIC OPIOID THERAPY - PUBLIC HEARING
2013-1025	02/08/2013 03/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LAURIE RICKETTS DEMPSEY & KINGSLAND	INDIVIDUAL RECS
2013-1026	02/08/2013 03/11/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ASHA LAMBATOS AVALON RISK MANAGEMENT INC	ENTRY #274-02109477 - NOTICE OF FDA ACTION #1
2013-1027	02/08/2013 03/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	VAL SAWYER MEDICINES CO	BOVINE THROMBIN/THROMBIN NOS/THROMBIN LOCAL SOL - ISRS 8532937, 8524621, 8504612
2013-1028	02/08/2013 03/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	PETER J TOMAO ESQ PETER J TOMAO ESQ	ALTUZAN, AVASTIN - TESTING TO DETERMINE IF THEY ARE COUNTERFEIT BEVACIZUMAB
2013-1029	02/08/2013 03/11/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JAMES K GIBSON JR PHD INTEGRITY LIFE SCIENCES	EXCITE MEDICALCORP, TAMPA,FL - EIR, 482, 483
2013-1030	02/08/2013 08/12/2013	FDA/OF/CFSAN/OCD/EOS/	ALISA BOUCHER BASF CORP	COGNIS, HENKEL CORP - VEGETABLE OIL ACIDS RECS
2013-1031	02/08/2013 03/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY ANDERSON SHIRE INC	WARNER CHILCOTT - DELZICOL NDA 204-412

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1032	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 1/21-25/13
2013-1033	02/08/2013 03/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MURALI GAVINI - 483S 2012 TO PRESENT
2013-1034	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 1/21-25/13
2013-1035	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SHCRAMP CanReg, Inc.	CLOSED FOI REQUESTS 1/21-25/13
2013-1036	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDIE INC	CLOSED FOI REQUESTS 1/21-25/13
2013-1037	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 1/21-25/13
2013-1038	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 1/21-25/13
2013-1039	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 1/21-25/13
2013-1040	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 1/21-25/13
2013-1041	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 1/21-25/13
2013-1042	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 1/21-25/13
2013-1043	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 1/21-25/13
2013-1044	02/08/2013 03/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 1/21-25/13
2013-1045	02/11/2013	FDA/OGROP/ORA/NE-FO/NYK-	Rachel Johnson	FISHER WALLACE, NEW YORK, NY - EIR MOST RECENT

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	03/12/2013	DO/NYK-DCB/	FOI Services, Inc.	
2013-1046	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NDA 17821 S0000 - APPROVAL PACKAGE OR SBA
2013-1047	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K880660, K863138
2013-1048	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Berks Nostrum Laboratories, Inc.	ANDA 201374 - FINAL APPROVAL LETTER
2013-1049	02/11/2013 03/12/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Ann Williams WILLIAMS, ANN B	AP PHARMA, INC, REDWOOD CITY, CA - 483, EIR, WARNING LETTER ETC
2013-1050	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Beverly Laird 3D Medical Concepts, LLC	K925635
2013-1051	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vinayagam Kannan JHP Pharmaceuticals, LLC	ANDA 011145 - SBA
2013-1052	02/11/2013 03/12/2013	FDA/OC/OES/DFOI/	Michael P. Krensavage Krensavage Asset Management LLC	CRYOLIFE, KENNESAW, GA - 483, WARNING LETTER
2013-1053	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/DDM/	Dale B. Adams Majestic Publishers	LINDANE - APPROVAL RECS
2013-1054	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeff O'Donnell Jr O'Donnell Partners	K101734
2013-1055	02/11/2013 03/12/2013	FDA/OC/OES/DFOI/	David Elder PAREXEL	FOIA REQUEST LOG (01/13/2013 - 02/07/2013)
2013-1056	02/11/2013	FDA/OMPT/CDER/GRP/DIDP/	Sherwin Sattarzadeh	NDA 21348

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	03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genzyme, A Sanofi Company	
2013-1057	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angela Vagotis Vagotis, Angela T	PAXIL - AERS
2013-1058	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Robert Blaskiewicz Robert Blaskiewicz	BURZYNSKI CLINIC, HOUSTON, TX - 483 (01/01/1985 - 12/31/2012)
2013-1059	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K870622, K102496, K052161 ETC
2013-1060	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K914972, K780568, K792441 ETC
2013-1061	02/11/2013 03/12/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OC/OES/DFOI/	Brian Harrison Brian Harrison	JHP PHARMACEUTICALS, ROCHESTER, MI - 483 (3/13/12- 3/29/12)
2013-1062	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Schultz The Dominion Group	NDA 204412 - SBA
2013-1063	02/11/2013 03/12/2013	CVM/OCD/	Dr. Diane Sudduth Biovance	NADA 014366
2013-1064	02/11/2013 03/12/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Lauren Farruggia Hyman, Phelps and McNamara	VELCADE - ORPHAN DRUG DESIGNATION FILE
2013-1065	02/11/2013 03/12/2013	OM/OMP/DODM/	Pauliana Hall PCH integrated Regulatory Services, Inc.	NONPRESCRIPTION DRUGS AND ARTHRITIS ADVISORY COMMITTEES BRIEFING DOCS 07/20/1999
2013-1066	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110617
2013-1067	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ashley Driscoll Diazyme Laboratories	K050574
2013-1068	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	ISR 6884596, 6912897, 7010082 ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1069	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122662
2013-1070	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Rachel Johnson FOI Services, Inc.	RICHARD WASSERMAN, DALLAS, TX - EIR (08/13-17/2012)
2013-1071	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103095
2013-1072	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tonya Bechtel Tarsa Therapeutics, Inc.	SANDOZ KUNDL, SCHAFTENAU - 483, WARNING LETTER (01/03/2011 - 09/28/2012)
2013-1073	02/11/2013 03/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Karen Weigand BEAUMONT HOSPITAL	BOVINE THROMBIN JMI PRODUCT 4B - AERS
2013-1074	02/11/2013 03/12/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Todd Phillips BECKLOFF ASSOCIATES INC	ADALIMUMAB - ORPHAN DESIGNATION REVIEW
2013-1075	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510(k) Summary for K834400
2013-1076	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K955349, K905496, K770835 ETC
2013-1077	02/11/2013 03/12/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Jarusha A. Bonitz Pharmaceutics International, Inc.	PHARMACEUTICS INTERNATIONAL INC, COCKEYSVILLE, MD, HUNT VALLEY, MD - EIR 05/19-28/10, 05/22/12-06/01/12, 10/01-22/12
2013-1078	02/11/2013 03/12/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	SHERRY RAE OREGON CHERRY GROWERS INC	DIANA FRUIT CO - WARNING LTR 7/27/11, CLOSING LTR 11/11/12
2013-1079	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 1/1- 31/13
2013-1080	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS, DAVID .	VALPROIC ACID; DILANTIN - AER

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1081	02/11/2013 03/12/2013	FDA/OC/OES/DFOI/	BURGESS, BERNIE	2007-3879
2013-1082	02/11/2013 03/12/2013	OC/OM/OMP/DDM/	LINDA COLLIER LINDA COLLIER	DKT 1988P-0179
2013-1083	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MURIS DEMIROVIC MANNING & NAPIER ADVISORS INC	NOVO NORDISK, NONO ALLE, BAGSVAERD DENMARK - 483 3/12-20/12
2013-1084	02/11/2013 03/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES L. FORD, Sr. JAMES LEE FORD	MCGHAN STYLE 468 SALINE FILLED BREAST IMPLANT - PMA APRVL
2013-1085	02/11/2013 03/12/2013	FDA/OMPT/CTP/OD/ FDA/OC/OPP/OP/	RICHARD G. DANNER JR ATTY	FDA SETS THE VALUE OF LIFE IN PROPOSING WARNING LABELS ON CIGARETTES - FINDINGS (CERTIFIED)
2013-1086	02/11/2013 03/12/2013	ORA/ORM/ ORA/ORM/	JOHNATHAN RICKMAN FDA NEWS	PHARMACEUTICALS, BIOLOGICS & MEDICAL DVC MFG, CLNC FACILITIES IN & OUTSIDE THE US - 483 1/1-31/13
2013-1087	02/11/2013 03/12/2013	OC/COS/OL/	JACK GILLUM ASSOCIATED PRESS	CORR TO SEN ROBERT MENENDEZ 1/07 TO PRESENT
2013-1088	02/11/2013 03/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN BLOCH JOHNS HOPKINS SCHOOL OF MEDICINE	ROXANE LABORATORIES - DIAZEPAM INTERSOL ANDA
2013-1089	02/11/2013 03/12/2013	FDA/OF/CFSAN/OCD/EOS/	NNEKA LEIBA ENVIRONMENTAL WORKING GROUP	PRIORITY-BASED ASSESSMENT OF FOOD ADDITIVES DATABASE
2013-1090	02/11/2013 03/12/2013	CVM/OCD/	HUGHES, LAURA	D-LIMONENE - AERS LAST 10-15 YRS
2013-1091	02/12/2013 03/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donna Seifarth Swiftwater Group, LLC	SUVEN LIFE SCIENCES, INDIA - QAP, 483, WARNING LETTERS ETC (01/01/2008 - 02/11/2013)
2013-1092	02/12/2013 03/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	joseph costa white mountain toxicology services llc	JUXTAPID NDA REVIEW

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1093	02/12/2013 03/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K033337, K974098, K980483
2013-1094	02/12/2013 03/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K023960
2013-1095	02/12/2013 03/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anil Goyal, PhD Qualiber, Inc.	GEMZAR IND
2013-1096	02/12/2013 03/13/2013	OC/OER/OPA/	XIN GE INDIVIDUAL	DR SHIMIN FANG - FDA APPROVAL FOR SPEECH
2013-1097	02/12/2013 03/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	CIVCO Medical Solutions CIVCO Medical Solutions	K120882
2013-1098	02/12/2013 03/13/2013	CVM/OCD/	Becky Armfield Novartis Animal Health US, Inc.	ANALYTICAL METHOD FOR DETERMINATION OF RACTOPAMINE HYDROCHLORIDE IN FEED SAMPLES
2013-1099	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (02/04/2013 - 02/08/2013)
2013-1100	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	SHARI SMITH Smith, Shari D	NEW ENGLAND COMPOUNDING CENTER - INVESTIGATIONS, REPORTS, LETTERS ETC (2002-PRESENT)
2013-1101	02/12/2013 03/13/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2013-1102	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	STEVEN F NAPOLITANO SKADDEN, ARPS, SLATE, MEAGHER & FLOM, LLP	2000-23647, 2000-23649, 2000-23650, ETC
2013-1103	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	BRENTON L HORNER HORNER & ASSOCIATES	UNREDACTED RECS
2013-1104	02/12/2013 03/13/2013	FDA/OF/CFSAN/OCD/EOS/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENTS - CAERS 138702, 138704, 138707, ETC 1/12 TO 8/12
2013-1105	02/12/2013 03/13/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CIN-	JOHN CREWSDON PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM ROXANE INC, DANBURY, CT 11/10/08; BOEHRINGER INGELHEIM ROXANE INC, COULMBUS,OH 5/6/09; BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA 5/13/09, ETC - EIRS

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		DO/CIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/		
2013-1106	02/12/2013 03/13/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	SGMP COMPANY LTD - ENTRY #EJK-0030361-1 TEST RESULTS
2013-1107	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	WILLIAM SARRAILLE SIDLEY AUSTIN LLP	ST JUDE MEDICAL - WARNING LTR RESP FOI REQUESTS 1/10/13 TO PRESENT
2013-1108	02/12/2013 03/13/2013	CVM/OCD/	RYAN T KEARNEY COZEN O'CONNOR PC	DEL MONTE FOODS - MILO'S KITCHEN CHICKEN JERKY, CHICKEN GRILLERS INVESTIGATION , TESTING, RECALL RECS
2013-1109	02/12/2013 03/13/2013	CVM/OCD/	RYAN T KEARNEY COZEN O'CONNOR PC	NESTLE PURINA PETCARE CO (WAGGIN TRAIN LLC) - CHICKEN JERKY PET TREATS RESIDUAL ANTIBIOTICS INVESTIGATION, TESTING, RECALL RECS
2013-1110	02/12/2013 03/13/2013	CVM/OCD/	RYAN T KEARNEY COZEN O'CONNOR PC	HARTZ MOUNTAIN CORP - CHICKEN CHEWS, OINKIE PIG SKIN TWISTS RESIDUAL ANTIBIOTICS INVESTIGATIONS, TESTING, RECALL RECS 2012
2013-1111	02/12/2013 03/13/2013	FDA/OC/OES/DFOI/	BOWEN #887936, ALTON	MEDWATCH FORM
2013-1112	02/13/2013 03/14/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-1113	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ OC/COS/OL/ FDA/OC/OES/DFOI/ ORA/ ORA/ OC/OL/	Michael Kaplan CBS NEWS/60 MINUTES	NEW ENGLAND COMPOUNDING CENTER - EMAILS, MEMOS, REPORTS
2013-1114	02/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K962696

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	03/14/2013		FOI Services, Inc.	
2013-1115	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K012990
2013-1116	02/13/2013 03/14/2013	OM/OMP/DODM/	Sara Warren Turner Environmental Law Clinic	STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION - REFERENCE 266 (01/03/2012 - 02/12/2013)
2013-1117	02/13/2013 03/14/2013	FDA/OO/OHR/	Viviana Bolton Viviana Bolton	HHS-FDA-14-533201
2013-1118	02/13/2013 03/14/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/ FDA/OC/OES/DFOI/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	BRAVO FARMS CHEESE, LLC - INSPECTION RECS 2010
2013-1119	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K033080
2013-1120	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K060888
2013-1121	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K103648
2013-1122	02/13/2013 03/14/2013	FDA/OF/CFSAN/OCD/EOS/	Alec White HEALTHCOR MANAGEMENT LP	MONSTER BEVERAGE, LIVING ESSENTIALS, RED BULL - CAERS (01/01/2000 - 02/12/2013)
2013-1123	02/13/2013 03/14/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Tomas Kiselak RA CAPITAL MANAGEMENT	DRUG PRODUCTS BY ACTIVE INGREDIENT, INDICATIONS FOR NDA 00623, 01285, 01885 ETC, LABELING, ETC
2013-1124	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K093661
2013-1125	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K123444
2013-1126	02/13/2013 03/14/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 203263

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2013-1127	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K970266
2013-1128	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marc C. Sanchez Contract In-House Counsel and Consultant	K102598, K011880, K091933
2013-1129	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deb Hogerman UCB, Inc.	NDA 21829 - MEDICAL, STATISTICAL, CMC REVIEWS (UNREDACTED)
2013-1130	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	BAUEREIND GMBH - VENOTRAIN COLOR COMPRESSION STOCKINGS & PANTYHOSE K860826
2013-1131	02/13/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	FOI Services, Inc.	CARIDIAN BCT INC - TRIMA ACCEL AUTOMATED BLOOD COMPONENT COLLECTION SYS BK080029
2013-1132	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FOI Services, Inc.	NDA 21077/S3
2013-1133	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	EXCEL TECH LTD - XLTEK EVOKED POTENTIAL HEADBOX MODEL EP16 SPS 1 STATIC PRESERVATION SOLUTION K992313
2013-1134	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	RYMED TECHNOLOGIES INC - IN VISION PLUS NANO W/NEUTRAL ADVANTAGE TECHNOLOGY K093489
2013-1135	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS, JEFFREY G	DURALSEAL SPINAL SEALANT - POST APRVL
2013-1136	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATERIALISE	D4D TECHNOLOGIES - E4D COMPASS K110511
2013-1137	02/13/2013 03/14/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	DAN HANSEN CONSTELLATION BRANDS	TURNER ROAD VINTNERS, LODI, CA - 482 11/28/12
2013-1138	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GEORGE R. SYZMANSKI LAW OFFICES OF GEORGE R SZYMANSKI	TYLENOL ARTHRITIS PAIN - CMPLNTS

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2013-1139	02/13/2013 03/14/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RICHARD N SHAPIRO LAW OFCS	HOWMEDICA OSTEONICS CORP, MAHWAH, NJ - K092406 2009, 2010, 2011, 2012
2013-1140	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L. GREEN, Ph.D. ROCKY MOUNTAIN POISON DRUG CTR	8481354, 8491845, 8492420, ETC - AERS
2013-1141	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	R MARK BORTNER SOCKOL & ASSOCIATES PA	PROFESSIONAL THERAPY PRODUCTS - DOCS
2013-1142	02/13/2013 03/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	P RICHARD WARBURTON CHEMDAQ INC	ADVANCED STERILIZATION PRODUCTS - STERRAD NX STERILIZER K042116
2013-1143	02/13/2013 03/14/2013	FDA/OF/CFSAN/OCD/EOS/	EASLEY 103481, KENT A	SOY - AER
2013-1144	02/13/2013 03/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	OSE RPTS OF INVESTIGATIONS OF RE-LY TRIAL
2013-1145	02/13/2013 03/14/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-1146	02/13/2013 03/14/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MARSH, JAMES	CMPLNT 128274
2013-1147	02/14/2013 03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeff O'Donnell Jr O'Donnell Partners	K072879, K040604
2013-1148	02/14/2013 03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bonnie Williams FOI Services, Inc.	K990144
2013-1149	02/14/2013 03/15/2013	FDA/OO/OFBA/OAGS/	William Hbranchak Neal R. Gross and Company	HHSF223201010156G
2013-1150	02/14/2013 03/15/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Sarah Schober BioNetwork	DIETARY SUPPLEMENT COMPANIES IN NORTH CAROLINA - 483 (02/13/2012 - 02/12/2013)
2013-1151	02/14/2013	FDA/OMPT/CDER/GRP/DIDP/	Norie Young	AVANDIA - COMPLAINTS 2007

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	03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WINTHROP UNIVERSITY HOSPITAL	
2013-1152	02/14/2013 03/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Suzanne Meintzer WILSON ELSEER MOSKOWITZ EDELMAN & DICKER LLP	SAN FRANCISCO HERB & NATURAL FOOD CO - ALL RECS (01/01/2011 - 12/31/2013)
2013-1153	02/14/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Lydia Mulvany MILWAUKEE JOURNAL SENTINEL	ECHO LAKE FOODS, BURLINGTON, WI - INSPECTION RECS 11/13/09
2013-1154	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	DUPHASTON - AERS
2013-1155	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125057 S0071
2013-1156	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	NDA 019722
2013-1157	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	ANDA 084264
2013-1158	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Barder Blend Therapeutics	NDA 21063, NDA 21492
2013-1159	02/14/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Gary Mackinnon Alvogen Group	BAYER HEALTHCARE - EIR (02/02/2009 - 03/08/2012)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		
2013-1160	02/14/2013 03/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	BRETT F CLEMENTS HERZFELD RUBIN	CFSAN EMAIL CONCERNING LISTERIA MONOCYTOGENES FOUND IN THRIFTY ICE CREAM (CERTIFIED)
2013-1161	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DOUGLAS F FORMAN DR REDDY'S LABORATORIES INC	DR REDDY'S LABORATORY INC - TIZANIDINE HCI TABS ANDA 76-286 CMLNT
2013-1162	02/14/2013 03/15/2013	CVM/OCD/	ELISABETTA LAMBERTINI UNIV OF MARYLAND	ANIMAL FEED INGREDIENTS, PET FOODS, PET TREATS - MICROBIOLOGICAL TESTS
2013-1163	02/14/2013 03/15/2013	FDA/OF/CFSAN/OCD/EOS/ OC/OER/OPA/ FDA/OC/OES/	BOBBY SCHOCHET OLSSON FRANK & WEEDA	COOPERATIVE AGREEMENTS BTWN FDA AND OUTSIDE PARTIES CONCERNING FOOD SAFETY 2009 TO PRESENT
2013-1164	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GAVIN ANDERSON AZAYA THERAPEUTICS INC	SUN PHARMA GLOBAL FZE - LIPODOX (DOXORUBICIN HCL LIPOSOMAL INJ) ANDA 203-263 RECS
2013-1165	02/14/2013 04/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ROBERT WELCH ANSAR INC	ANSAR INC - MTG MINS, NOTES, TRANS, ETC
2013-1166	02/14/2013 03/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH H SAUNDERS SAUNDERS & WALKER PA	BIOMET INC, WARSAW, IN; BIOMET UK LTD, SOUTH WALES, UK - EIRS, 482S, 483S; MOM HIP ARTHROPLASTY SYS CONGRESSIONAL CORR, ETC
2013-1167	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRENDERGAST, JOYCE E	CHANTIX (VERENICLINE) - AERS 6/1/12 TO 2/5/13

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2013-1168	02/14/2013 03/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAMIE J FINIZIO BASCOMBE FINIZIO LAW CENTER	STEAMER SPORT 888WA WHEELCHAIR - CMPLNTS, RECALL RECS, SAFETY ALERTS, ETC
2013-1169	02/14/2013 03/15/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC	SHAMPOO CONDITIONERS HAIR PREPARATIONS BILL OF LADING # SMLU3261238A - RECS
2013-1170	02/14/2013 03/15/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE ZETETIC	HAIR SHAMPOO & CONDITIONERS BILL OF LADING #SMLU3270088A - RECS
2013-1171	02/14/2013 03/15/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE ZETETIC	SHAMPOO CONDITIONERS HAIR PREPARATIONS BILL OF LADING # SMLU3249949A - RECS
2013-1172	02/14/2013 03/15/2013	FDA/OF/CFSAN/OCD/EOS/	BETTY BEHRENS REGAN ZAMBRI LONG & BERTRAM PLLC	INDIVIDUAL RECS
2013-1173	02/14/2013 03/15/2013	FDA/OF/CFSAN/OCD/EOS/	BETTY BEHRENS REGAN ZAMBRI LONG & BERTRAM PLLC	INDIVIDUAL RECS
2013-1174	02/14/2013 03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	BIOMET - HIP PROTHESIS MDRS
2013-1175	02/14/2013 03/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Doe J	FLU VACCINE - INDIVIDUAL RECS
2013-1176	02/14/2013 03/15/2013	CVM/OCD/	HUGHES, LAURA	D-LIMONENE - AERS
2013-1177	02/14/2013 03/15/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	AMERICAN CASIEN CO, BURLINGTON, NJ - INSPS 2007 TO 2011
2013-1178	02/14/2013 03/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	NATROL INC, CHATSWORTH, CA - INSPS 2007 TO 2011
2013-1179	02/14/2013 03/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	COMMERCIAL PROTEINS CORP, LAKE ARROWHEAD, CA - INSPS 2007 TO 2011
2013-1180	02/14/2013	FDA/OGROP/ORA/CE-FO/NWJ-	BRYAN W BLACK	FCC PRODUCTS, LIVINGSTON, NJ - INSPS 2007 TO 2011

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	03/15/2013	DO/NWJ-CB/	DERREVERE, HAWAKES, BLACK ET AL	
2013-1181	02/14/2013 03/15/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	BRYAN W BLACK DERREVERE, HAWAKES, BLACK ET AL	NATURE'S PRODUCTS INC, SUNRISE, FL - INSPS 2007 TO 2011
2013-1182	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	NOVO NORDISK A/S, BAGSVAERD, DENMARK - 483 3/12-20/12
2013-1183	02/14/2013 03/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	NOVO NORDISK A/S, BAGSVAERD, DENMARK - EIR 3/12-20/12
2013-1184	02/14/2013 03/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Willis, Jerome	SCHWARZ PHARMA - FORMS IN WHICH REGLAN IS MANUFACTURED
2013-1185	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne Grenier TERUMO CARDIOVASCULAR SYSTEMS CORP	K992785
2013-1186	02/15/2013 03/18/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeff Overley Law360	HOSPIRA INC - 483 (07/01/2012 - 02/13/2013)
2013-1187	02/15/2013 03/18/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	QUESERIA BENDITA, YAKIMA, WA - EIR (01/01/2010 - 12/31/2010)
2013-1188	02/15/2013 03/18/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carla Johnson ASSOCIATED PRESS	HOSPIRA INC - 483 (01/01/2011 - 02/14/2013)

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2013-1189	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Suzanne Grenier TERUMO CARDIOVASCULAR SYSTEMS CORP	K922356
2013-1190	02/15/2013 03/18/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	SETTON INTERNATIONAL FOODS, INC., COMMACK, NY - EIR 2009
2013-1191	02/15/2013 03/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam Deisinger Rocah Brown	REQUIP - DEAR HEALTHCARE PROFESSIONAL LETTERS
2013-1192	02/15/2013 04/12/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Kathleen Rowe Rowe, Kathleen	BONFILS BLOOD CENTER, DENVER, CO - 483 (02/01/2010 - 02/14/2013)
2013-1193	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	BASIC FOOD FLAVORS, LAS VEGAS, NV - EIR 2010
2013-1194	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Imran Karim Imran Karim	K120737
2013-1195	02/15/2013 03/18/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	AZTECA, BROOKLYN, NY - EIR 2010
2013-1196	02/15/2013 03/18/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Kenneth Cusack CERTIFIED LABORATORIES INC	52309790336 - LAB RESULTS
2013-1197	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	SETTON PISTACHIO, TERRA BELLA, CA - EIR 2009
2013-1198	02/15/2013 03/18/2013	FDA/OF/CFSAN/OCD/EOS/	Natasha Singer THE NEW YORK TIMES	DIETARY SUPPLEMENTS CONTAINING DMAA - ADVERSE EVENTS (01/01/2009 - 02/14/2013)
2013-1199	02/15/2013 03/18/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	QUESERIA CHIPILO, PASSAIC, NJ - EIR 2010

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2013-1200	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Imran karim Imran Karim	K103472
2013-1201	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Susan Zakarian PRA INTERNATIONAL	ANDREW L CHAN, SACRAMENTO, CA - 483 (04/09/2012 - 05/31/2012) ;
2013-1202	02/15/2013 03/18/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Sarah Schober BioNetwork	GAIA HERBS, BREVARD, NC - 483 2/16/11
2013-1203	02/15/2013 03/18/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SUBSTANTIAL EQUIVALENCE DATA
2013-1204	02/15/2013 03/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	NDA 016635 - APPROVAL HISTORY, LABELING
2013-1205	02/15/2013 03/18/2013	OM/OMP/DODM/	Sarah Sorscher PUBLIC CITIZEN	INTRA-AORTIC BALLOON PUMP DEVICES; EXTRACORPOREAL MEMBRANE OXYGENATION DEVICES; EXTERNAL CARDIAC COMPRESSOR DEVICES - COMMENTS; FDA-2009-M-0101-0093 (UNREDACTED)
2013-1206	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	SETTON INTERNATIONAL FOODS, INC, TERRA BELLA, CA - EIR (01/01/2010 - 12/31/2010)
2013-1207	02/15/2013 03/18/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	PEANUT CORPORATION, LYNCHBURG, VA - EIR (01/01/2009 - 12/31/2009)
2013-1208	02/15/2013 03/18/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	PEREGRINA CHEESE CORPORATION, BROOKLYN, NY - EIR (01/01/2009 - 12/31/2009)
2013-1209	02/15/2013 03/18/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Thomas Sanders COLLEGE OF WILLIAM AND MARY	WRIGHT COUNTY EGG AKA QUALITY EGG, GALT, IA - EIR (01/01/2010 - 12/31/2010)
2013-1210	02/15/2013 03/18/2013	CVM/OCD/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ ORA/ ORA/	Dane Martin Shank & Hamilton, P.C.	MILO'S KITCHEN - CORR BETWEEN FDA AND NY STATE DEPT OF AGRICULTURE; INTERNAL CORR; CORR TO OR FROM MILO'S KITCHEN, DEL MONTE CORP, ETC

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		FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OC/OES/DFOI/		
2013-1211	02/15/2013 03/18/2013	CVM/OCD/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Dane Martin Shank & Hamilton, P.C.	WAGGIN TRAIN, CANYON CREEK - COMM BETWEEN FDA AND NY STATE DEPT OF AGRICULTURE; INTERNAL CORR; CORR WITH WAGGIN TRAIN, NESTLE PURINA PETCARE COMPANY ETC
2013-1212	02/15/2013 03/18/2013	FDA/OF/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	NOS ENERGY DRINKS - AERS (02/23/2007 - 02/15/2013)
2013-1213	02/15/2013 03/18/2013	FDA/OF/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	NO FEAR ENERGY DRINKS - AERS (02/16/2007 - 02/15/2013)
2013-1214	02/15/2013 03/18/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Doe J	CMPLNT 130363
2013-1215	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN REEVES MAKO SURGICAL CORP	STANMORE IMPLANTS WORLDWIDE LTD - SCULPTOR ROBOTIC GUIDANCE ARM K121765
2013-1216	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LAURA KILGORE WATSON LABORATORIES INC	GONAL F RFF PEN NDA 21-684/S-019, 21-684/S023, 21-684/S-024 APRVL LTRS
2013-1217	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL TREAS HOLLWOG LLC	ETHICON INC - TEMPORARY CARDIAC PACING WIRE K822155
2013-1218	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BROTHER 1273700, HENRI	VALTERAN (DICLOFENAC), ALTRAM (TRAMADOL) - AERS
2013-1219	02/15/2013 03/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	SALIX PHARMACEUTICALS - RELISTOR (METHYLNALTREXONE BROMIDE) NDA 21-964 CORR 12/6/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1220	02/15/2013 03/18/2013	FDA/OC/OES/DFOI/	HEATHER GALE OFW LAW	UNTITLED LTRS 12/1/11 TO PRESENT
2013-1221	02/15/2013 03/18/2013	FDA/OC/OES/DFOI/	HEATHER GALE OFW LAW	PREVIOUSLY RELEASED UNTITLED LTRS FROM CDRH
2013-1222	02/15/2013 03/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	K BARNES BIOPHARM INSIGHT	NOVO - NORDISK A/S - 483, CO RESP 12/12/12
2013-1223	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	KARL NITTINGER DENTSPLY INTERNATIONAL	DMC COMPOSITE 2 K103351
2013-1224	02/15/2013 03/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SEAN GREENWOOD GAUTHIER HOUGHTALING ET AL	INDIVIDUAL RECS - VAERS
2013-1225	02/15/2013 03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	STRYKER IRELAND LTD OSTEONICS - EIR, FORM 3500, FORM 3500A
2013-1226	02/15/2013 03/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	PERRIGO ISRAEL - MINOXIDIL ANDA 91-344 SBA
2013-1227	02/15/2013 03/18/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-1228	02/15/2013 03/18/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	DONALD N. BLUE ZETETIC	ENTRY NO WFX12307470
2013-1229	02/15/2013 03/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - CAERS 7/1/10 TO 6/30/11
2013-1230	02/15/2013 03/18/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS - VAERS (CERTIFIED)
2013-1231	02/15/2013	FDA/OGROP/ORA/NE-FO/NWE-	ANNE E. SCHMIDT	OLIVE GARDEN, FOXBORO, MA - FOOD POISONNG 1/8/13

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	03/18/2013	DO/NWE-CB/	JIM BRADY AND ASSOCIATES PC	
2013-1232	02/15/2013 03/18/2013	OC/COS/OL/ OC/OL/	JENNIFER HABERKORN POLITICO	CORR BTWN HOUSE, SENATE & HHS 11/6/12 TO 2/14/13
2013-1233	02/15/2013 03/18/2013	OC/COS/OES/ OC/COS/OES/	JOSEPH DEDVUKAJ JOSEPH DEDVUKAJ FIRM PC	BELVIQ (LORCASERIN HCI) - DRUG CLASSIFICATION EVALUATION & SCHEDULING PROCESS RECS, CORR, ETC
2013-1234	02/15/2013 03/18/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	GABRIEL BRIER QUINN EMANUEL ET AL	NDA 00-623, 01-285, 01-885
2013-1235	02/19/2013 03/19/2013	FDA/OF/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	FULL THROTTLE ENERGY DRINK - AERS (02/02/2007 - 02/14/2013)
2013-1236	02/19/2013 03/19/2013	FDA/OF/CFSAN/OCD/EOS/	wendy crossland CROSSLAND, WENDY	AMP ENERGY DRINKS - AERS (02/15/2007 - 02/14/2013)
2013-1237	02/19/2013 03/19/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Michael A. Carome, M.D. PUBLIC CITIZEN'S HEALTH RESEARCH GROUP	REVECO INTERNATIONAL, FULLERTON, CA; ADVANCED AESTHETIC CONCEPTS, FORT WORTH, TX; PROFIT SOLUTIONS MD, FORT WORTH, TX - 483 12/31/09 TO PRESENT
2013-1238	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K910944
2013-1239	02/19/2013 03/19/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	FEDERAL EXCISE TAX PAYED BY INDUSTRY FOR REMOVAL OF CIGARETTE PAPER AND TUBES
2013-1240	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Emily Settlemaier Reliable Biopharmaceutical Corporation	PHARMACOSMOS ROERVANGSVEJ, HOLBAEK, DENMARK - MOST RECENT EIR
2013-1241	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OM/OMP/DODM/	Chris Cano Agile Therapeutics	OBSTETRICS AND GYNECOLOGY ADVISORY COMMITTEE MEETINGS - MEETING MINUTES, AGENDAS 1975
2013-1242	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Wong St. Jude Medical	BOSTON SCIENTIFIC PRECISION SPECTRA SYSTEM - SUBMISSION, LABELING (P030017 S134)

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2013-1243	02/19/2013 03/19/2013	FDA/OF/CFSAN/OCD/EOS/ OC/COS/OES/ OC/COS/OES/ OC/OCC/	Gregory Jaffe Center for Science in the Public Interest	GENETICALLY ENGINEERED ORGANISMS - MEETINGS BETWEEN FDA AND INDUSTRY ON OR AROUND 01/11/13
2013-1244	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rebecca Shames HOGAN LOVELLS LLP	K122389, K111454, K102541
2013-1245	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K894369
2013-1246	02/19/2013 03/19/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Lorcan Carleton Carleton, Lorcan	CONSUMER COMPLAINT 130581
2013-1247	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Slvia Aguiar Oliveira Rosa São José Hospital	DONEPEZIL - AERS
2013-1248	02/19/2013 03/19/2013	FDA/OF/CFSAN/OCD/EOS/	Lynn P. Tordo Thor Specialties, Inc.	FCN 1169
2013-1249	02/19/2013 03/19/2013	FDA/OC/OES/DFOI/	Kelly Yamanouchi Atlanta Journal-Constitution	GATE GOURMET, ATLANTA, GA - 483 (10/31/2012 - 02/15/2013)
2013-1250	02/19/2013 03/19/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Kimberly Kiker Calhoun City Schools	BEST EXPRESS FOODS, INC - RECS, WARNING LETTER, CLEARANCE
2013-1251	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Dr. Frederick O. Cope Dr. Frederick O. Cope	AMYVID - APPLICATION, ANALYSIS, REVIEW
2013-1252	02/19/2013 03/19/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Anne Crossley Reckitt Benckiser Healthcare UK	ADVIL COLD & FLU COATED TABLETS - NDA
2013-1253	02/19/2013 03/19/2013	FDA/OO/OHR/	Jairaj Mehta JM Pharma Solutions, LLC	RUSSELL G KATZ, MD - RESUME

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2013-1254	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. Yossi Muncher Dr. Yossi Muncher	K931946
2013-1255	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gabriel Zimmerman The Sheba Medical Center	CIPRODEX(R) - SBA
2013-1256	02/19/2013 03/19/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ ORA/OCI/ ORA/OCI/ FDA/OC/OES/DFOI/	Louis Jefferson PROMETHEUS LABS	PROMETHEUS LABORATORIES, INC - COMPLAINTS, INVESTIGATIONS, RESULTS OF COMPLAINTS (01/01/2008 - 01/01/2013)
2013-1257	02/19/2013 03/19/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Caroline Hartill RTI Biologics, Inc	UNIVERSITY OF MIAMI TISSUE BANK - 483 (02/01/2012 - 02/18/2013)
2013-1258	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ellen Zimmerman ClearView Diagnostics Incorporated	K070477
2013-1259	02/19/2013 03/19/2013	CVM/OCD/	Larry Stobbs Stobbs Consulting Inc.	FEED ASSAY METHOD FOR MGA
2013-1260	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125160 S080 - APPROVAL LETTER, LABELING, MEDICAL REVIEW, ETC
2013-1261	02/19/2013 03/19/2013	CVM/OCD/	Larry Stobbs Stobbs Consulting Inc.	RACTOPAMINE ASSAY METHOD B04372
2013-1262	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	PULMOZYNE (DORMASE ALFA) BLA 103532 APRVL LTR, LBLG, MOR, ETC
2013-1263	02/19/2013 05/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	RUTH WOLFSON PHD BIOLOGICS CONSULTING GROUP	GLASSIA - ORIGINAL BLA, CLNCL PHARMACOLOGY RVW, SAFETY TESTING, ETC
2013-1264	02/19/2013 03/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CORNELL, CAITLIN	ANDROSCIENCE CORP - TOPICAL ASC-19 CREAM FOR ACNE IND

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2013-1265	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUSAN PRIEST HARTLEY HAMPTON PC	INDIVIDUAL RECS
2013-1266	02/19/2013 03/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	THAO PHAN CARL ZEISS MEDITEC INC	RIGHTMEDICAL PRODUCTS LLC - RIGHTON SOOM SLIT LAMP NS-2D K110129; TOPCON MEDICAL SYSTEMS INC - TOPCON SLIT LAMP SL-2G K110489, ETC
2013-1267	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEIM PHARMACEUTICALS INC - PRDAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S004 CORR, MINS, NOTES, ETC
2013-1268	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	UCERIS NDA 203-634 - APRVL LTR, LBLG, MOR, ETC
2013-1269	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA VIBOCH KEARNY VENTURE PARTNERS	FERRIC NITRATE - TRADE NAMES
2013-1270	02/19/2013 03/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KUHLMANN, DAVID	DIVISION OF NEUROLOGY PRODUCTS - MEMBERS CONFLICT OF INTEREST RECS
2013-1271	02/19/2013 03/19/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	STELLA K HERRERA GRIFOLS BIOLOGICALS INC	HOSPIRA, ROCKY MOUNT, NC - EIRS, 483S 1/11 TO 1/13
2013-1272	02/19/2013 03/19/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	J HOWISON SCHROEDER NEURO KINETICS INC	NEURO KINETICS INC, PITTSBURGH, PA - EIR 4/15-20/10
2013-1273	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim McCarthy Kingdon Capital Management	XTANDI - FAERS (09/10/2012 - 02/19/2013)
2013-1274	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103795 S1004 (ENBREL)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1275	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Emily Settlemaier Reliable Biopharmaceutical Corporation	ST PHARM CO LTD, GYEONGGI-DO, KOREA - EIR MOST RECENT
2013-1276	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S5256 (RITUXAN)
2013-1277	02/20/2013 03/20/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Michael Laszek Healthpoint Biotherapeutics	LONZA WALKERVILLE, WALKERVILLE, MD - 483 AND/OR EIR (12/01/2011 - 12/31/2011)
2013-1278	02/20/2013 03/20/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ CVM/OCD/	Jenn Strathman WEWS-TV - Jenn Strathman	BENEFUL, PURINA DOG FOOD - CONSUMER COMPLAINTS, INSPECTION REPORTS, MEMOS ETC (01/01/2010 - 02/18/2013)
2013-1279	02/20/2013 03/20/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Brian Walsworth NA	DR JONATHAN FIELDING, LOS ANGELES, CA - ALL CORR (01/01/2002 - 02/15/2013)
2013-1280	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Frederick O. Cope Dr. Frederick O. Cope	DATSCAN - COMMENTS, SUMMARIES
2013-1281	02/20/2013	FDA/OF/CFRAN/OCD/EOS/	Andrew Breza	OIL OF MELALEUCA INC - REGULATORY ACTIONS

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	03/20/2013		AMERICAN UNIVERSITY	(01/01/1981 - 12/01/1986)
2013-1282	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (02/11/2013 to 02/15/2013)
2013-1283	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alina Poulsen Happy Products llc	K920240
2013-1284	02/20/2013 03/20/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 429, 545, 594 ETC
2013-1285	02/20/2013 03/20/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	CENTOCOR, RADNOR, PA - EIR, 483 09/08
2013-1286	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ratinder Brar St. Jude Medical	P960009 S051
2013-1287	02/20/2013 03/20/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Tyler Kenyon NORTHCOAST RESEARCH	HILL-ROM, BATESVILLE, IN - MONTHLY UPDATES (10/30/2012 - 02/19/2013)
2013-1288	02/20/2013 03/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Cohen BMJ	EXENATIDE, LIRAGLUTIDE, SITIGLIPTIN - REPORTS, STUDIES, MEMOS ETC
2013-1289	02/20/2013 03/20/2013	FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/	Mike Smith Truth in Food/Custom Publications LLC	MILK SAMPLING FIELD ASSIGNMENTS - SUMMARY OR INTERIM STATUS REPORTS
2013-1290	02/20/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Raymond R. Blanche NST Consulting, LLC	K113097
2013-1291	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-968 SPREADSHEET
2013-1292	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM H. WALL WALL MEDICAL INC	WALL MEDICAL INC, BUFORD, GA - SET ADMINISTRATION INTRAVASCULAR K940689
2013-1293	02/20/2013 03/20/2013	CVM/OCD/	LAMBERTINI, ELISBETTA	SALMONELLA - ANIMAL FEED INGREDIENTS, PET FOODS 2002 TO 2009
2013-1294	02/20/2013 03/20/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	FLORES MOJICA, FELICITA	CONSUMER CMLPNT
2013-1295	02/20/2013 03/20/2013	CVM/OCD/	TOM NASH MUCKROCK NEWS	GENETICALLY ENGINEERED SALMON 2000 TO 2012
2013-1296	02/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	DAILY LOG 1/28/13 - 2/1/12

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	03/20/2013		CanReg, Inc.	
2013-1297	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	WEEKLY CLOSED LOG 1/28/13 - 2/1/13
2013-1298	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/14-18/13
2013-1299	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/14-18/13
2013-1300	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 1/7-11/13
2013-1301	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 1/7-11/13
2013-1302	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/28/13 - 2/1/13
2013-1303	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED LOG 1/28/13 - 2/1/13
2013-1304	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED LOG 1/14-18/13
2013-1305	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/14-18/13
2013-1306	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 1/7-11/13
2013-1307	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	Lauren Brieze Williams, Craig	2012-1997
2013-1308	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED LOG 1/7-11/13
2013-1309	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Felicia Ruley TechLab Inc	K982315
2013-1310	02/20/2013 03/20/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jairaj U. Mehta JM Pharma Solutions, LLC	ORGANIZATIONAL CHART DIVISION OF NEUROLOGY PRODUCTS, DIVISION OF PSYCHIATRY PRODUCTS (02/20/2008 - 02/20/2013)
2013-1311	02/20/2013 03/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bradley Wendorff UW-Madison dept Biomedical Eng.	K061256

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2013-1312	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 1/14-18/13
2013-1313	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/14-18/13
2013-1314	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/7-11/13
2013-1315	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 1/7-11/13
2013-1316	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED LOG 1/28-2/1/13
2013-1317	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 1/28-2/1/13
2013-1318	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	FDA NEWS	DAILY LOG 1/28-2/1/13
2013-1319	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 1/14-18/13
2013-1320	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED LOG 1/7-11/13
2013-1321	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 1/7-11/13
2013-1322	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 1/14-18/13
2013-1323	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 1/28-2/1/13
2013-1324	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/7-11/13
2013-1325	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/14-18/13
2013-1326	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 1/28-2/1/13
2013-1327	02/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN	DAILY LOG 1/14-18/13

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	03/20/2013		WOLTERS KLUWER LAW & BUSINESS	
2013-1328	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/14-18/13
2013-1329	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/7-11/13
2013-1330	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/7-11/13
2013-1331	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/28/13 - 2/1/13
2013-1332	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 1/28/13 - 2/1/13
2013-1333	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/7-11/13
2013-1334	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/14-18/13
2013-1335	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 1/28/13 - 2/1/13
2013-1336	02/20/2013 03/20/2013	CVM/OCD/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ ORA/ ORA/	REBECCA FIELD EMERSON MITTS LAW LLC	WEDGEWOOD VILLAGE PHARMACY INC - WARNING LTR SINCE 1/09
2013-1337	02/20/2013 03/20/2013	CVM/OCD/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	REBECCA FIELD EMERSON MITTS LAW LLC	DIRECT VET MARKETING INC - WARNING LTRS SINCE 1/09
2013-1338	02/20/2013 03/20/2013	CVM/OCD/ ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	NICOLE A. VENO IZARD NOBEL LLP	PURINA BENEFUL - AERS 2007 TO PRESENT

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		FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/		
2013-1339	02/20/2013 03/20/2013	FDA/OC/OES/DFOI/	DNALD E. SEGAL ALSTON & BIRD LLP	CRYOLIFE INC, KENNESAW, GA - EIR, 483, WARNING LTR, CORR 1/12 TO PRESENT
2013-1340	02/20/2013 03/20/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	MEADE, DORIS .	UPSLABS LLC, DALLAS, TX - 483 2/7-21/12
2013-1341	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANa Maria Saaibi Biomedika Consulting	K062270
2013-1342	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Felicia Ruley TechLab Inc	K083464
2013-1343	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Darren Reeves DP DISTRIBUTION & CONSULTING, LLC	K082554
2013-1344	02/21/2013 03/21/2013	CVM/OCD/ OC/OCC/	Genna Reed Food & Water Watch	MTG BETWEEN MICHAEL DOYLE AND FDA RE OXITEC - RECS, AGENDA, NOTES, ETC
2013-1345	02/21/2013 03/21/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Aaron Diamant WSB-TV	GATE GOURMET, ATLANTA, GA - EIR, 483, WARNING LETTER ETC (06/01/2009 - 12/31/2012)
2013-1346	02/21/2013 03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/OCC/	ANGIE SALVATIERRA US LEGAL SUPPORT INC	ANTHREX - TIGHTROPE CLNCL STUDIES, APRVL RECS, SS&E, ETC
2013-1347	02/21/2013 03/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RAVI DESHPARIDE ACINO PRODUCTS LLC	TARO PHARMS - TERCONAZOLE VAGINAL SUPPOSITORY ANDA 77-553 SBA
2013-1348	02/21/2013	FDA/OF/CFSAN/OCD/EOS/	VERONICA S KNAPP	PARTIALLY HYDROGENATED VEGETABLE OILS - GRAS

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	03/21/2013	FDA/OC/OPP/OP/	HOGAN LOVELLS LLP	STATUS
2013-1349	02/21/2013	FDA/OMPT/CDER/ORP/DIDP/	HOLLY J BAYNE	INC AGENCY BV, LOOSDRECHT, NETHERLANDS - EIR 9/10-13/12 CORR, TRANS, MTG NOTES, ETC
	03/21/2013	FDA/OMPT/CDER/ORP/DIDP/	BAYNE & ASSOCIATES	
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OF/CFSAN/OCD/EOS/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OF/CFSAN/OCD/EOS/		
2013-1350	02/21/2013	FDA/OC/OES/DFOI/		INDIVIDUAL RECS
	03/21/2013		Doe J	
2013-1351	02/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	MICHELE K POWERS	JOHNS HOPKINS MEDICINE - PHARMACODYNAMIC TRIAL OF PRE-PROSTATECTOMY LOVASTATIN RPTS, APRVL, MEMOS, ETC
	03/21/2013	FDA/OMPT/CDER/ORP/DIDP/	BRASSEL ALEXANDER & RICE LLC	
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
		FDA/OMPT/CDER/ORP/DIDP/		
2013-1352	02/21/2013		ANGELA SMYTH	CAERS 160966
	03/21/2013		IOVATE HEALTH SCIENCES INTERNATIONAL INC	
2013-1353	02/21/2013	FDA/OF/CFSAN/OCD/EOS/	SHERRY L FISHER	VISIT TO PAPER BOARD PLANTS IN CONNECTION WITH PCB FINDINGS IN TOTAL DIET SAMPLE 7/14/71 (CERTIFIED)
	03/21/2013	OM/OMP/DODM/	HUNTON & WILLIAMS LLP	
2013-1354	02/21/2013	CVM/OCD/	JANET L DEFILIPPIS	BACITRACIN, LINCOMYCIN, AMPROLIUM HCI - RECS
	03/21/2013		HERRIS GROUP LLC	
2013-1355	02/21/2013	FDA/OC/OES/DFOI/	ROSS D PLONT	CARDINAL HEALTH - EXCHANGE TRANSFUSION TRAY FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
	03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	GRUEL MILLS NIMS & PYLMAN LLP	
2013-1356	02/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROSS D PLONT	CARDINAL HEALTH - EXCHANGE TRANSFUSION TRAY STOPCOCK FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
	03/21/2013	FDA/OC/OES/DFOI/	GRUEL MILLS NIMS & PYLMAN LLP	
2013-1357	02/21/2013	FDA/OC/OES/DFOI/	ROSS D PLONT	ALLEGIANCE HEALTHCARE CORP - EXCHANGE TRANSFUSION PROCEDURE TRAY FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
	03/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	GRUEL MILLS NIMS & PYLMAN LLP	

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2013-1358	02/21/2013 03/21/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	ROSS D PLONT GRUEL MILLS NIMS & PYLMAN LLP	ALLEGIANCE HEALTHCARE - PHARMASEAL EXCHANGE TRANSFUSION TRAY FORM FDA 3500A, MEMOS, RPTS, NARRATIVES, ETC
2013-1359	02/22/2013 03/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Dave Braggs ISIS Pharmaceuticals	PYRAMID LABORATORIES, COSTA MEDA, CA - EIR (01/01/2010 - 01/01/2013)
2013-1360	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Wolff SHIRE PHARMACEUTICALS INC	MEDWATCH REPORTS WITH CONTACT INFORMATION UNREDACTED
2013-1361	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary Liquori, Esq. Powers & Liquori, Attys at Law	METHADONE - UPDATED GUIDELINES ON PRESCRIBING, PACKAGE INSERTS, CONVERSION CHARTS
2013-1362	02/22/2013 03/22/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS (01/01/08 - 02/20/2013)
2013-1363	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adam P. Deisinger, Esq. Roach, Brown, McCarthy & Gruber, P.C.	REQUIP - CERTIFIED RECS
2013-1364	02/22/2013 03/22/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Alyssa Smirz BioGenesis Nutraceuticals Inc	GARDEN STATE NUTRITIONALS - EIR (01/01/2007 - 02/21/2013)
2013-1365	02/22/2013 03/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Jason DeVooght Jason DeVooght	EXCEL MEDICAL PRODUCTS, FENTON, MI - 483 (07/03/2012 - 02/21/2013)
2013-1366	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edward J Kaplan MD Microspherix LLC	ONCOGEL PACLITAXEL/REGEL ABSORBABLE GEL - PRECLINICAL IN VITRO AND IN VIVO TOXICOLOGY AND PHARMACOKINETIC TESTING
2013-1367	02/22/2013 03/22/2013	FDA/OC/OES/DFOI/	Amy Kincanon LEXISNEXIS COURTLINK INC	2013-1018
2013-1368	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Philip Almeter University of Kentucky - UK Chandler	THROMBIN-JMI, RECOTHROM - AERS

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		FDA/OMPT/CBER/OCOD/DDOM/ALFB/		
2013-1369	02/22/2013 03/22/2013	FDA/OF/CFSAN/OCD/EOS/	Haruya Kato Kato Business Consulting	BASF - UNTITLED LETTER RECS (02/21/2013 - 03/15/2013)
2013-1370	02/22/2013 03/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Tim McCarthy Kingdon Capital Management	ZYTIGA - AERS
2013-1371	02/22/2013 03/22/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Amy Kincanon LEXISNEXIS COURTLINK INC	2012-8401
2013-1372	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Colquitt Standly & Hamilton, LLP	K982347, K983853, K984458 ETC - MAUDE REPORTS
2013-1373	02/22/2013 03/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Edward J Kaplan MD Microspherix LLC	GLIADEL - PRECLINICAL IN VITRO AND IN VIVO TOXICOLOGY AND PHARMACOKINETIC STUDIES
2013-1374	02/22/2013 03/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Sandeep Patil Theravance, Inc.	FENCAMFAMIN - DEA SCHEDULE IV STATUS; NDA/IND; SAE
2013-1375	02/22/2013 03/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OC/OCC/	Steven Napolitano Napolitano, Steven	VASCEPA - NCE RECS (06/01/2013 - 02/21/2013)
2013-1376	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	CYNOSURE INC - AFFIRM DO DIODE LASER K101601
2013-1377	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	CYNOSURE INC - YAG FAMILY LASER K031690
2013-1378	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	CYNOSURE INC - YAG MIR FAMILY LASER K053421
2013-1379	02/22/2013 03/22/2013	FDA/OGROP/ORAN/NE-FO/NWE-DO/NWE-CB/	MARC CHAFETZ BELTWAY LAW GROUP LLP	FRESNIUS - GRANUFLO; NATURLYTE COMPLIANCE

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2013-1380	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA KILGORE WATSON LABORATORIES INC	GONAL F RFF NDA 21-684/S-028; NDA 21-684/S-029
2013-1381	02/22/2013 03/22/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	ONA SCANDURRA COUNTRY LIFE LLC	US PHARMA LAB INC, NORTH BRUNSWICK, NJ; ASPIRE PHARMACEUTICALS, SOMERSET NJ - 483, EIR 6/09 TO PRESENT
2013-1382	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KRISTIN DAVENPORT GOODWIN PROCTER LLP	CARDIOGEN 82 NDA 19-414 - APRVL RECS, RVWS
2013-1383	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATE CADDY DSM Bright Science. Brighter living	POSH CHEMICALS PRIVATE LTD, INDIA - EIR, 483 CO RESP SINCE 2008
2013-1384	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS, HOME HEMODIALYSIS MACHINE K121421
2013-1385	02/22/2013 03/22/2013	FDA/OO/OHR/	KENDRA L. SHELTON PROADVOCATE GROUP	HOWARD SKLAMBERG; ALYSON SABEN; DALI BORDEN - DECLARATION OF STATEMENT W/EMPLOYEE
2013-1386	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	ITC, PISCATAWAY, NJ - K040190 SUBMISSION
2013-1387	02/22/2013 03/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	MICROCOAGULATION ACTIVATED CLOTTING TIME PLUS TEST K941007 1994
2013-1388	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GVOZD, VLADIMIR	CATER WALLACE INC - FELBATOL (FELBAMATE) SUBMISSION
2013-1389	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA HOBBS LEXIS NEXIS COURTLINK INC	NORAMCO, RHODES TECHNOLOGIES, JOHNSON MATTHEY - 14 HYDROXYCODEINONE (UNSATURATED KETONE IMPURITY) CORR SINCE 2010, oxycodone hydrochloride
2013-1390	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A. THURSTON , Jr. THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S-001; 20-971/S-023 - CORR

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1391	02/22/2013 03/22/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	VIRGIL L. UMPHENOUR INTERIOR ALASKA FISH PROCESSORS INC	BONSILA, ANVIK, AK - EIR 2009
2013-1392	02/22/2013 03/22/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BARRY J. GAINEY GAINEY & MCKENNA	RANBAXY - ATORVASTATIN (GENERIC LIPITOR) CORR
2013-1393	02/22/2013 03/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM W. HOWARD, Ph.D., MBA ALITAIR PHARMACEUTICALS INC	ROBERTS PHARMACEUTICAL CORP, EATONTOWN, NJ - MAXIVENT (DOXOFYLLINE) NDA
2013-1394	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7067
2013-1395	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Shibani Malhotra Malhotra, Shibani	HOSPIRA, INC, LAKE FOREST, IL - 483, UNTITLED LETTER (06/01/2012 - 02/22/2013)
2013-1396	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K941546, K980176, K890100
2013-1397	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/	Lauren A. Farruggia Hyman, Phelps and McNamara	US AGENT FOR REGISTERED FOREIGN FOOD FACILITIES
2013-1398	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K932673, K910859, K882378 ETC
2013-1399	02/25/2013 03/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Daryl DeValerio Andrews BERMAN DEVALERIO ET AL	ABIOMED, INC - COMMUNICATIONS WITH FDA RE IMPELLA RECOVER LP 2.5 PERCUTANEOUS CARDIAC SUPPORT SYSTEM
2013-1400	02/25/2013 03/25/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Kelly Jabbal AccessClosure, Inc.	ACCESSCLOSURE, MOUNTAIN VIEW, CA - EIR (08/01/2011 - 08/30/2011)
2013-1401	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/	Josh Kleckner Alfa Laval Tank Equipment	FCN 302, FCN 297
2013-1402	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-227

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2013-1403	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/	Robert Weissman Saretsky Katz Dranoff & Glass, LLP	DMAA CONTAINING PRODUCTS - AERS (06/01/2012 - 02/22/2013)
2013-1404	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7254
2013-1405	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sami Woo C & H International Co.	K020851
2013-1406	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K903315, K830654, K912573 ETC
2013-1407	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erica Winter Erica Winter, Noven Pharmaceuticals	ANSAID - PHARMACOLOGY REVIEW, MEDICAL/SAFETY REVIEW, CLINICAL PHARMACOLOGY
2013-1408	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K921777, K934722, K934311 ETC
2013-1409	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandon Stempo B. Braun Medical Inc.	NDA 17643 - SBA, MEDICAL REVIEW, CLINICAL/PHARMACOLOGY REVIEW
2013-1410	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K896095, K862158, K900773 ETC
2013-1411	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 203263
2013-1412	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HAMELN PHARMACEUTICALS, HAMELN, GERMANY - EIR, 483 (06/04/12-06/14/12)
2013-1413	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brandon Stempo B. Braun Medical Inc.	NDA 18786
2013-1414	02/25/2013	ORA/	Shibani Malhotra	HOSPIRA, INC - IMPORT BAN (11/02/2012 - 02/22/2013)

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	03/25/2013	ORA/ FDA/OGROP/ORA/ORO/DIOP/	Malhotra, Shibani	
2013-1415	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JANUVIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES AND AMENDMENTS
2013-1416	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Mlodzik Boehringer Ingelheim Vetmedica, Inc.	AUROBINDO PHARMA LTD, HYDERABAD, INDIA - EIR (09/17/2012 - 02/22/2013)
2013-1417	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eduardo E. Kelly MD Steptoe Therapeutics Inc.	TBO -FILGRASTIM - SBA
2013-1418	02/25/2013 03/25/2013	ORA/ ORA/ CVM/OCD/	Phyllis Entis eFoodAlert	KASEL ASSOCIATED INDUSTRIES, DENVER, CO - 483, 423(A) LETTER
2013-1419	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Muelly Michael Muelly	K081304
2013-1420	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Benjamin P. Mouton McGlynn, Glisson & Mouton	AMNISURE INTERNATIONAL, LLC - MEDICAL DEVICE CORRECTION LETTER 10/01/07
2013-1421	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIN E SEDER VENABLE LLP	AZO GESIC, AZO SEPTIC, AZO STANDARD, ETC - AERS
2013-1422	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	EDWARD BRENNAN FLAVOR DEVELOPMENT CORP	FLAVOR DEVELOPMENT CORP, NORWOOD, NJ - EIR 11/11
2013-1423	02/25/2013 03/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHNATHAN RICKMAN FDA NEWS	GLOCHEM INDUSTRIES LTD, ANDRHA PRADESH, INDIA; SEVEN STAR PHARMACEUTICAL CO LTD, TAIPEI HSIENG, TAIWAN; BEIJING TAIYANG PHARMACEUTICAL INDUSTRY CO LTD, BEIJING, CHINA, ETC - 483S 1/1-31/13
2013-1424	02/25/2013 03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOHNATHAN RICKMAN FDA NEWS	BIOMET CO LTD, SEOUL, KOREAN; RUBIMED AG, HERGISWIL, SWITZERLAND - 483S 1/1-31/13

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2013-1425	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	JOHNATHAN RICKMAN FDANEWS	PRIME ENTERPRISES INC, HIALEAH, FL; BELCHER PHARMACEUTICALS LLC, LARGO, FL; GADAL LABORATORIES INC, MIAMI, FL, ETC - 483S 1/1-31/13
2013-1426	02/25/2013 03/25/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JOHNATHAN RICKMAN FDANEWS	LINCARE INC, OTTAWA, KS; MOBIUS THERAPEUTICS LLC, ST LOUIS, MO; RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO, ETC - 483S 1/1-31/13
2013-1427	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	JOHNATHAN RICKMAN FDANEWS	ALPHA MEDICAL INSTRUMENTS LLC, MISSION VIEJO, CA; HELIX MEDICAL LLC, CARPINTERIA, CA; ACUFOCUS INC, IRVINE, CA - 483S 1/1-31/13
2013-1428	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	JOHNATHAN RICKMAN FDANEWS	BIRCHWOOD LABORATORIES INC, EDEN PRAIRIE, MN; FRONTIER MEDICAL PRODUCTS INC, PORT WASHINGTON, WI; ELECTRO KINETIC TECHNOLOGIES LLC, GERMANTOWN, WI - 483S 1/1-31/13
2013-1429	02/25/2013 03/25/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	JOHNATHAN RICKMAN FDA NEWS	BIO-CONCEPT LABORATORIES INC, SALEM, NH; BFS PHARMA INC, RANDOLPH, MA; CENTRAL ADMIXTURE PHARMACY SERVICES INC, WOBURN, MA, ETC - 483S 1/1-31/13
2013-1430	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JOHNATHAN RICKMAN FDANEWS	CONTRACT COATING INC, HACKENSACK, NJ; MEDI PHYSICS INC, SOUTHFIELD PLAINFIELD, NJ; OMEGA PACKAGING CORP, TOTOWA, NJ, ETC - 483S 1/1-31/13
2013-1431	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	JOHNATHAN RICKMAN FDANEWS	LIFESOUTH COMMUNITY BLOOD CENTERS INC, MADISON, AL; PETNET SOLUTIONS INC, COVINGTON, LA; GAC TECHNO CENTER, BIRMINGHAM, AL - 483S 1/1-31/13
2013-1432	02/25/2013 03/25/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JOHNATHAN RICKMAN FDANEWS	AMES GOLDSMITH CORP, GLENS FALLS, NY; ADVANCE PHARMACEUTICAL INC, HOLTSTVILLE, NY; FRESENIUS KABI USA LLC, GRAND ISLAND, NY, ETC - 483S 1/1-31/13
2013-1433	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHNATHAN RICKMAN FDANEWS	DRECHER ENTERPRISES INC, UPPER DARBY, PA; PIRAMAL CRITICAL CARE INC, BETHLEHEM, PA - 483S 1/1-31/13
2013-1434	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	JOHNATHAN RICKMAN FDANEWS	XLUMENA INC, MOUNTAIN VIEW, CA; AMEDICA BIOTECH INC, HAYWARD, CA; INVUITY INC, SAN FRANCISCO, CA - 483S 1/1-31/13
2013-1435	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	JOHNATHAN RICKMAN FDA NEWS	MSD INTERNATIONAL GMBH PUERTO RICO BRANCH LLC, ARECIBO, PR; CARDINAL HEALTH PR 218 INC, ANASCO, PR - 483S 1/1-31/13
2013-1436	02/25/2013 03/25/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	JOHNATHAN RICKMAN FDANEWS	BEZWECKEN INC, WILSONVILLE, OR; COMFORT ACRYLICS INC, CAMAS, WA; VANGUARD EMS INC, BEAVERTON, OR, ETC - 483S 1/1-31/13
2013-1437	02/25/2013 03/25/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	JOHNATHAN RICKMAN FDANEWS	WAYNE CONCEPT MANUFACTURING CO INC, FORT WAYNE, IN; CARACO PHARMACEUTICAL LABORATORIES INC, DETROIT, MI - 483S 1/1-31/13
2013-1438	02/25/2013	FDA/OGROP/ORASW-FO/DEN-	JOHNATHAN RICKMAN	SHIPPET ENTERPRISES LTD, CENTENNIAL, CO - 483S

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	03/25/2013	DO/DEN-CB/	FDA NEWS	1/1-31/13
2013-1439	02/25/2013 03/25/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	SCOTT WILKIN UBS GLOBAL ASSET MANAGEMENT	INTEGRA, ANASCO, PR - 483 10/12 TO 11/12
2013-1440	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	SUNTORY LTD - ACUTE TOXICITY TEST HGT-94-23; HGT-94-26
2013-1441	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/	FAUST 01B2507, BRIAN	POTASSIUM - AER
2013-1442	02/25/2013 03/25/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	JOHNATHAN RICKMAN FDANEWS	MID-CONTINENT PACKAGING INC,ENID, OH; FRESENIUS MEDICAL CARE NORTH AMERICA TEXAS, IRVING, TX; RAPID TRAUMA LLC, SAN ANTONIO, TX, ETC - 43S 1/1-31/13
2013-1443	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 7362873, 7388962, 7389714, ETC
2013-1444	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 8438483, 8438487, 8438491 ETC
2013-1445	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 8122655, 8130611, 8130617 ETC
2013-1446	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EARL GOEHRING, Jr. DEGGE GROUP LTD	ISRS 7616861, 7621864, 7630337, ETC
2013-1447	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASO/DIOP/	MICHAEL G. ATKINS Atkins Intellectual Property, PLLC	B&B INTERNATIONAL, NY, NY - VIOLATIONS 200 TO 10/04
2013-1448	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASO/DIOP/	MICHAEL G. ATKINS Atkins Intellectual Property, PLLC	OST AQUA ZAO, CHERNOGOLOVKA, RUSSIA - VIOLATIONS 2000 TO PRESENT
2013-1449	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASO/DIOP/	MICHAEL G. ATKINS Atkins Intellectual Property, PLLC	AQUA LIFE , CHERMOGOLOVKA, RUSSIA - VIOLATIONS 2000 TO PRESENT
2013-1450	02/25/2013	FDA/OGROP/ORACE-FO/CIN-	JOHNATHAN RICKMAN	WRENCARE, MIDDLETOWN, OH; DIAGNOSTIC HYBRIDS

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	03/25/2013	DO/CIN-CB/	FDANEWS	INC, ATHENS, OH; SCM TRUE AIR TECHNOLOGIES LLC, LOUISVILLE, KY, ETC - 483S
2013-1451	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHNATHAN RICKMAN FDA NEWS	CORPAK MEDSYSTEMS INC, BUFFALO GROVE, IL; ALMA LASERS INC, BUFFALO GROVE, IL - 483S 1/1-31/13
2013-1452	02/25/2013 03/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	TINA MARIE HARRIS TRAUB LIEBERMAN STRAUS ET AL	FRANCKS LAB INC - BRILLIANT BLUE G; TRIAMCINOLONE INJECTION
2013-1453	02/25/2013 03/25/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	JOHNATHAN RICKMAN FDA NEWS	JOHNS HOPKINS UNIV PET CENTER, BALTIMORE, MD; HUMAN BIOSCIENCES INC, GAITHERSBURG, MD; VISIONARY OPTICS LLC, FRONT ROYAL, VA - 483S 1/1-31/13
2013-1454	02/25/2013 03/25/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JOHNATHAN RICKMAN FDANEWS	MEDI-FARE DRUG AND HOME HEALTH CENTER, BLACKSBURG, SC; NCONTRACT SURGICAL INC, MORRISVILLE, NC - 483S 1/1-31/13
2013-1455	02/25/2013 03/25/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	RICHARD H. WAGNER WAGNER LYNN ET AL	DA VITA HEALTHCARE PARTNERS INC - INVESTIGATION RECS
2013-1456	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	FLYNN P. CAREY GALLAGHER & KENNEDY PA	THERMOLIFE INTERNATIONAL LLC - PUMP BOL, E BOL, T, BOL - CORR, INVESTIGATIONS, AER 1/05 TO 12/11
2013-1457	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI REQUESTS 2/4-8/13
2013-1458	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/4-8/13
2013-1459	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI REQUESTS 2/4-8/13
2013-1460	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/4-8/13
2013-1461	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/4-8/13
2013-1462	02/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN	CLOSED FOI REQUESTS 2/4-8/13

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	03/25/2013		WOLTERS KLUWER LAW & BUSINESS	
2013-1463	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOI REQUESTS 2/4-8/13
2013-1464	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/4-8/13
2013-1465	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 2/4-8/13
2013-1466	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI REQUESTS 2/4-8/13
2013-1467	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 2/4-8/13
2013-1468	02/25/2013 03/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES WASHINGTON INFORMATION SOURCE	DAILY LOG 2/4-8/13
2013-1469	02/25/2013 03/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (02/01/2013 - 02/25/2013)
2013-1470	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Stocking Stocking, John	K081697
2013-1471	02/26/2013 03/26/2013	FDA/OC/OES/DFOI/	Brent Arbogast Brent Arbogast	FREQUENTLY REQUESTED RECORDS
2013-1472	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K120834, K060967, K924125 ETC
2013-1473	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K063696, K041191, K010566 ETC
2013-1474	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ann Thomas TauTona Group	K980431
2013-1475	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ann Thomas TauTona Group	K992991
2013-1476	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ann Thomas TauTona Group	K013625
2013-1477	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ann Thomas TauTona Group	K050246

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2013-1478	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OF/CFSAN/OCD/EOS/	Brad N Sommer SOMMER LAW GROUP, PC	RODAN & FIELDS AMP MR MICRO-NEEDLE ROLLER - CLASSIFICATION RECS
2013-1479	02/26/2013 03/26/2013	FDA/OGROP/ORR/SE-FO/FLA- DO/FLA-CB/	P.Caro TissueNet	ALLOGRAFT INNOVATIONS, GAINESVILLE, FL - 483 (11/01/2012 - 02/25/2013)
2013-1480	02/26/2013 03/26/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDA NEWS	FOIA LOG (02/18/2013 - 02/22/2013)
2013-1481	02/26/2013 03/26/2013	FDA/OMPT/CTP/OD/	Donald Graff CELERION	TAR AND NICOTINE CONTENT OF CIGARETTES
2013-1482	02/26/2013 03/26/2013	CVM/OCD/	Rachel Johnson FOI Services, Inc.	TYPE C FEED ASSAY FOR NICARB 25%
2013-1483	02/26/2013 03/26/2013	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Doe J	INVESTIGATION RECS
2013-1484	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5009109
2013-1485	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5027038
2013-1486	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5016600
2013-1487	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5009261
2013-1488	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5017757
2013-1489	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5012580
2013-1490	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5019215
2013-1491	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5019473
2013-1492	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5005390
2013-1493	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD NIPRO Diagnostics	MW5009108
2013-1494	02/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD	MW5002772

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	03/26/2013		NIPRO Diagnostics	
2013-1495	02/26/2013	FDA/OC/OES/DFOI/	HEATHER GALE	CDRH UNTITLED LTRS 12/1/11 TO PRESENT
	03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLSSON FRANK WEEDA TERMAN MATZ PC	
2013-1496	02/26/2013	FDA/OC/OES/DFOI/	HEATHER GALE	CDRH UNTITLED LTRS
	03/26/2013		OLSSON FRANK WEEDA TERMAN MATZ PC	
2013-1497	02/26/2013	FDA/OMPT/CDER/ORP/DIDP/	SCOTT #JY1512/L-27, SEAN	ASTRAZENECA PHARMS - SEROQUEL OFF-LABEL MARKETING, SETTLEMENT AGREEMENT, Cmplnts, etc
	03/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCC/ FDA/OC/OES/DFOI/		
2013-1498	02/26/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	DANIEL G JARCHO MCKENNA LONG & ALDRIDGE LLP	NATURAL SELECTION FOODS, EARTHBOUND FARMS, TAYLOR FARMS - EIRS, 483S 1/06 TO PRESENT
	04/17/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/		
2013-1499	02/26/2013	FDA/OMPT/CDER/ORP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PRADAXA - AERS; BOEHRINGER INGELHEIM, DANBURY, CT; COLUMBUS, OH, PETERSBURG, VA - EIRS; RE-LY TRIALS - CLNCL SITES, NAMES OF INVESTIGATORS, ETC
	03/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/		
2013-1500	02/26/2013	FDA/OMPT/CDER/ORP/DIDP/	Doe J	NAPROXEN - AERS
	03/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1501	02/26/2013 03/26/2013	FDA/OF/CFSAN/OCD/EOS/	STEVE OTWELL PHD UNIV OF FLORIDA COLLEGE OF AGRICULTURE AND LIFE SCIENCES	ASSESSMENT OF THE NET EFFECTS OF FISH CONSUMPTION DURING PREGNACY - FINAL DRAFT
2013-1502	02/26/2013 03/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CLARK, CHRISTY	PROPRANOLOL - AERS
2013-1503	02/26/2013 03/26/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/OCI/ ORA/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	E KIRK WOOD WOOD LAW FIRM LLC	IDS SPORTS - MASS TABS INVESTIGATION RECS
2013-1504	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FAYGIE SACKS SMC DIRECT LLC	BINAX CLEARVIEW ADVANCED STRAP A K091489 - CLIA WAIVER APPL
2013-1505	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY STANIFORD SMC DIRECT LLC	WAMPOLE LABS - CLEARVIEW HCG COMBO K992187 CLIA WAIVER APPL
2013-1506	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FAYGIE SACKS SMC DIRECT LLC	BINAX - NOW STREP A CARD K960712 CLIA WAIVER APPL
2013-1507	02/26/2013 03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FAYGIE SACKS SMC DIRECT LLC	WAMPOLE LABS - CLEARVIEW HCG II K953988 CLIA WAIVER APPL
2013-1508	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-5936
2013-1509	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-6045
2013-1510	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-2938
2013-1511	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-6015
2013-1512	02/27/2013 03/27/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	John D. Morris 4LIFE RESEARCH LC	CSBNUTRITION, LINDON, UT - WARNING LETER, 483 (07/02/2012 - 12/28/2012)

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2013-1513	02/27/2013 03/27/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Patricia Mullins The SWAIM390 Companies	WISDOM PROTEINS INC, SAN DIEGO, CA - INSPECTION RECS (01/01/2009 - 12/31/2012)
2013-1514	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Wong St. Jude Medical	P030017 S134
2013-1515	02/27/2013 03/27/2013	FDA/OF/CFSAN/OCD/EOS/	Tony G. Mendoza Crowell & Moring LLP	FCN 246
2013-1516	02/27/2013 03/27/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	Alec White HEALTHCOR MANAGEMENT LP	APP PHARMACEUTICALS, LLC, GRAND ISLAND - CORR (01/01/2010 - 02/26/2013)
2013-1517	02/27/2013 03/27/2013	ORA/ ORA/	Richard Newman RND Services, LLC	CENTRAL ADMIXTURE PHARMACY SERVICES, INC, WOBURN, MA - 483 2013
2013-1518	02/27/2013 03/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fang Liu G&W Labs	ANDA 064022, ANDA 062124 - SBA
2013-1519	02/27/2013 03/27/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Cathy Kitzmiller Eisai Inc.	EISAI, RESEARCH TRIANGLE PARK, NC - EIR (07/01/2011 - 12/31/2011)
2013-1520	02/27/2013 03/27/2013	FDA/OF/CFSAN/OCD/EOS/	Justin O'Connor Justin O'Connor	ASPARTAME IN MILK, DAIRY PRODUCTS (01/01/2008 - 02/26/2013)
2013-1521	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bill Chin Masep Infini	K111862
2013-1522	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110012
2013-1523	02/27/2013 03/27/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leonard Krause Compliance Specialists, LLC	SIMILASAN CORPORATION, HIGHLANDS RANCH, CO; SIMILASAN AG, JONEN SWITZERLAND - 483 (04/08/2011 - 05/27/2011)
2013-1524	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K100818
2013-1525	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bill Chin Masep Infini	K102915
2013-1526	02/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ginger R Neil	K090957

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	03/27/2013		Ripple LLC	
2013-1527	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ginger R Neil Ripple LLC	K123255
2013-1528	02/27/2013 03/27/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jeff Varelman Jeff Varelman	KING BIO INC, ASHEVILLE, NC - INSPECTION RECORDS, ADVERSE EVENT REPORTS, ETC (01/01/2009 - 01/01/2013)
2013-1529	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Ginger R Neil Ripple LLC	K082629
2013-1530	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina M. Babos IPD ANALYTICS LLC	LETTER DATED 04/28/1988 FROM C PECK OF CDER RE 5 YEAR STATUTORY EXCLUSIVITY
2013-1531	02/27/2013 03/27/2013	CVM/OCD/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bryan Sanders N/A	CIS-TESTOSTERONE - APPROVAL RECS, DATES FOR HUMAN AND ANIMAL DRUGS; DESI RECS
2013-1532	02/27/2013 03/27/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	DIAZ, BRENDA LIZ	SAMPLE RESULTS
2013-1533	02/27/2013 03/27/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT 2001P-0586, 2002P-0469
2013-1534	02/27/2013 03/27/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	CARLO CASULO, MD ASCEND CAPITAL LLC	ABIOMED - CLOSE OUT LTR 6/10/11
2013-1535	02/27/2013 03/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	CMPLNT 10846
2013-1536	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/	Doe J	SCHIIYGOHRENIA - CAUSES
2013-1537	02/27/2013	FDA/OC/OES/DFOI/	ELLOITT FAVUS, MD	2013 DRUG REQUEST LOG

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	03/27/2013		FAVUS INSTITUTIONAL RESEARCH LLC	
2013-1538	02/27/2013 03/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB (ICLUSIG) - AER 2012 TO PRESENT
2013-1539	02/27/2013 03/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	OAKES, TIMOTHY	TANDEM DIABETES CARE INC - INSULIN DELIVERY SYS K111210
2013-1540	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	ACCLARENT INC, MENLO PK, CA - K082188
2013-1541	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	ACCLARENT INC, MENLO PARK, CA - K103595
2013-1542	02/27/2013 03/27/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	HOSPIRA INC, LAKE FOREST, IL - 483 1/13
2013-1543	02/27/2013 03/27/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC	ENTRY NO EHP00765942
2013-1544	02/27/2013 03/27/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KURT E. LEE JUDD ULRICH ET AL	SILVER BAY LLC - RECALL, AER
2013-1545	02/27/2013 03/27/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KURT E. LEE JUDD ULRICH ET AL	QUASAR BIO-TECH INC - RECALL, AER
2013-1546	02/27/2013 03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	GARY O'HARA THERMOMEDICS	THERMOMEDICS - K080759, K090361
2013-1547	02/27/2013 03/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2012-8987
2013-1548	02/27/2013 03/27/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	K. MICHELLE VASSALLO LINCARE INC	PURE OXYGEN LLC, OHIO; PA - 483, EIR, WARNING LTR 1/05 TO PRESENT

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2013-1549	02/27/2013 03/27/2013	ORA/OCI/ ORA/OCI/	GEORGE A. STAMBOULIDIS BAKER & HOSTETLER, LLP	DR ANTHONY GALEA - INVESTIGATION
2013-1550	02/27/2013 03/27/2013	FDA/OF/CFSAN/OCD/EOS/	EASLEY 103481, KENT A	SOY - AER
2013-1551	02/28/2013 03/28/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Matt Cheatham SL Chapman LLC	AMS 800 URINARY CONTROL PUMP WITH INHIBIZONE; RESERVOIR, PENILE PROSTHESIS 100 CC, IMPLANT, EXTENDER 100 CC ETC - ALERTS, RECALLS, SAGETY COMMUNICATIONS
2013-1552	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K792281, K820193, K923657
2013-1553	02/28/2013 03/28/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Jeffrey A. Pribanic, Esquire Pribanic & Pribanic, L.L.C.	INDIVIDUAL RECS
2013-1554	02/28/2013 03/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Lauren Specter NBC NEWS	DMAA - AERS (01/01/2006 - 02/27/2013)
2013-1555	02/28/2013 03/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Sarah Tracy UNIVERSITY OF TORONTO	MSG - AERS (01/01/1985 - 12/31/2012)
2013-1556	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Emily Morris Georgia Tech Research Institute	K944765
2013-1557	02/28/2013 03/28/2013	FDA/OF/CFSAN/OCD/EOS/	Lauren Specter NBC NEWS	USPLABS, JACK3D - AERS (2006-2013)
2013-1558	02/28/2013 03/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Gaspar UH Hilo College of Pharmacy	IMNM WITH HMG-COA REDUCTASE INHIBITOR THERAPY - AERS (01/01/1987 - 02/27/2013)
2013-1559	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Caitlin Senter Remington Medical, Inc.	K990519

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2013-1560	02/28/2013 03/28/2013	FDA/OC/OES/DFOI/	WHITE, HORTENSE S	SPICES, FOOD DYES - RECS
2013-1561	02/28/2013 03/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MARY D LEWIS MARY D LEWIS LLC	INDIVIDUAL RECS
2013-1562	02/28/2013 03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	NATALIE N SANDERS LATHAM & WATKINS LLP	KARMELSONIX (ISONEA) - PERSONAL WHEEZOMETER K090863; PULMOTRACK 5050 K101022
2013-1563	02/28/2013 03/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OM/OMP/DODM/	JOHN E FITZPATRICK III ODOM & DES ROCHES LLP	DKT 2012P-1028; ACTAVIS ELIZABETH LLC - ANDA 91-422, AMNEAL PHARMS - ANDA 203-136
2013-1564	02/28/2013 03/28/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	MEADE, DORIS .	BEEHIVE BOTANICALS INC, HAYWARD, WI - 483 7/23-25/12
2013-1565	02/28/2013 03/28/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MAYA FOA REPRIEVE	PENTOBARBITAL SODIUM POWDER - IMPORT RECS 7/12 TO PRESENT
2013-1566	02/28/2013 03/28/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	HEIDI L REILLY CLARKE LAW OFFICES	INDIVIDUAL RECS
2013-1567	02/28/2013 03/28/2013	FDA/OF/CFSAN/OCD/EOS/	ELIZABETH FLOCK MUCKROCK NEWS	OCEANA - SEAFOOD FRAUD IN AMERICA RECS 2/21/13
2013-1568	02/28/2013 03/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ISOSORBIDE (DINITRATE AND/OR MONONITRATE) - API/BULK PROD LISTINGS 1/10 TO PRESENT
2013-1569	02/28/2013 03/28/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	ANDRES G MONTERO SUAREZ & MONTERO LAW OFCS	MALTA HATUEY BEVERAGE - RECALL RECS, RPTS, PRESS RELEASES, ETC
2013-1570	03/01/2013	FDA/OMPT/CDER/ORP/DIDP/	Alan Buchwald, M.D.	BODY BUILDING PRODUCTS AND HIDDEN STEROIDS:

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	03/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alan Buchwald, M.D., Inc.	ENFORCEMENT BARRIERS - REFERENCES, ADVERSE EVENTS
2013-1571	03/01/2013 03/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Garet Heintz Pacira Pharmaceuticals, Inc.	EXPAREL - SBA
2013-1572	03/01/2013 03/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	LABOR L+S, GERMANY - INVESTIGATOR DIARIES (01/24/2013 - 02/01/2013)
2013-1573	03/01/2013 03/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	LABOR L+S, GERMANY - EIR, 483, RESPONSE, ETC (01/24/2013 - 02/01/2013)
2013-1574	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	peter m stevens md Morphographics, LLC	K031493
2013-1575	03/01/2013 03/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Naomi Wells UNIVERSITY OF ILLINOIS AT CHICAGO	SAVELLA - AERS (01/01/2003 - 02/28/2013)
2013-1576	03/01/2013 05/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Dr. Paul Effler Paul Effler MD	SUMMARY BASIS FOR REGULATORY ACTION CSL LIMITED INFLUENZA VIRUS VACCINE
2013-1577	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bernie R Silvers ORIGEN BIOMEDICAL	K991864
2013-1578	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121270
2013-1579	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121270
2013-1580	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY PAGNOZZI SMC DIRECT LLC	BINAX, CLEARVIEW ADVANCED STREP A MODEL 737-430 K091489; BINAX, NOW STREP A TEST K960712; ACON, QUICK A RAPID TEST STRIP K010582
2013-1581	03/01/2013 04/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JENNIFER O'BRIEN BATTELLE	INDIVIDUAL RECS

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2013-1582	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LENORE FAULHABER, Ph.D. PROCTER & GAMBLE COMPANY	UROMED IMPRESS SOFTPATCH - UNREDACTED
2013-1583	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI LOG 2/11-15/13
2013-1584	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/11-15/13
2013-1585	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/11-15/13
2013-1586	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI LOG 2/11-15/13
2013-1587	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 2/11-15/13
2013-1588	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOI REQUESTS 2/11-15/13
2013-1589	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/11-15/13
2013-1590	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	CLOSED REQUESTS LOG 2/11-15/13
2013-1591	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON SCHRAMP CanReg, Inc.	DAILY LOG 2/11-15/13
2013-1592	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 2/11-15/13
2013-1593	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 2/11-15/13
2013-1594	03/01/2013 03/29/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED REQUESTS LOG 2/11-15/13
2013-1595	03/01/2013 03/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NOTICES SENT BY FDA IN 1985 TO MANUFACTURERS OF NEUROLEPTIC DRUGS REGARDING LABEL WARNINGS FOR TARDIVE DYSKINESIA
2013-1596	03/01/2013	FDA/OGROP/ORACE-FO/MIN-	Jeff White	AMERICAN PRECLINICAL SERVICES, MINNEAPOLIS, MN -

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	03/29/2013	DO/MIN-CB/	Saint Joseph's Translational Research In	483 (01/01/2011 - 03/01/2013)
2013-1597	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Gabriel Brier QUINN EMANUEL ET AL	PRESCRIPTION DRUG WRAP-UP LIST
2013-1598	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dana Annunziato NOVEN PHARMACEUTICALS INC	NDA 018766 - MEDICAL RVW
2013-1599	03/01/2013 03/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	A full copy of the 510(k) medical device K083087 and K052643 Ei Inc.	K083087, K052643
2013-1600	03/01/2013 03/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 202608
2013-1601	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Molly Juhlin Oregon Health Sciences University	VASCEPA - SUMMARY REVIEW
2013-1602	03/04/2013 04/01/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Mitchell A. Goldstein Babener & Associates	PULSE HEALTH, LLC - WARNING LETTER RECS (01/03/2012 - 02/28/2013)
2013-1603	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	5663073 6221105 7285819 ETC - MEDWATCH RPTS (SINGULAIR)
2013-1604	03/04/2013 04/01/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Pete Bevan Chromogenex Technologies Limited	ADVANCED PHOTONICS SYSTEMS LED SYSTEMS - FDA ACTIONS (10/29/2012 - 02/28/2013)
2013-1605	03/04/2013 06/14/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Professor Paul Effler Paul Effler, MD	CSL INFLUENZA VACCINE - REGISTRATION, LICENSE RECS (01/01/1989 - 01/01/2012)
2013-1606	03/04/2013 04/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING &	SBA 20589, S009, 015, 017, 019

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUBMISSIONS	
2013-1607	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Langreth BLOOMBERG NEWS	MEDSUN SAFETY SURVEY ON SURGEONS AND HOSPITAL USE OF INTUITIVE SURGICAL ROBOTIC EQUIPMENT AND MEDICAL PRODUCT SAFETY NETWORK; MEDICAL PRODUCT SAFETY NETWORK SMALL SAMPLE SURVEY ON DA VINCI SURGICAL SYSTEM
2013-1608	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20589
2013-1609	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Minnich B. Braun Medical Inc.	K111275
2013-1610	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bridgette Kunst B&H Consulting Services, Inc.	NDA 020207 - SBA
2013-1611	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bridgette Kunst B&H Consulting Services, Inc.	NDA 014691 - SBA
2013-1612	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PEDIATRIC WRITTEN REQUEST FOR STUDIES AND RELATED AMENDMENTS FOR VICTOZA
2013-1613	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PEDIATRIC WRITTEN REQUEST FOR STUDIES AND RELATED AMENDMENTS FOR BYETTA
2013-1614	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PEDIATRIC WRITTEN REQUEST FOR STUDIES AND RELATED AMENDMENTS FOR AMARYL
2013-1615	03/04/2013	FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton	SBA 20944 S002, 003

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	04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INC RESEARCH CONSULTING & SUBMISSIONS	
2013-1616	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20944 - RECS NOT INCLUDED IN RELEASABLE SBA
2013-1617	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kim Thorson Medical Products Laboratories, Inc.(MPL)	ANDA 202470 SEQUENCE 0001
2013-1618	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Cano Agile Therapeutics	NDA 17354, NDA 17355, NDA 17875 - MEDICAL OFFICE REVIEW
2013-1619	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Beasley Beasley, Richard	NDA 20723
2013-1620	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OC/OES/DFOI/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NELSON BACH USA LTD - CORR, COMM WITH FDA
2013-1621	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Minnich B. Braun Medical Inc.	K110535
2013-1622	03/04/2013 04/01/2013	ORA/ORM/ ORA/ORM/	Jason DeYoung WESTERN MICHIGAN UNIVERSITY	LIST OF INSPECTIONS IN MICHIGAN, INDIANA, OHIO (01/04/2010 - 03/01/2013)
2013-1623	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ellen Zimmerman ClearView Diagnostics Incorporated	K012084
2013-1624	03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Barry Newberger	LENEX LASERS INC, ALCON LENEX, INC, ALCON

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	04/01/2013	FDA/OC/OES/DFOI/	Conley Rose P.C.	RESEARCH, LTD - 510K RECS
2013-1625	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Josh Sweren FARALLON CAPITAL MANAGEMENT LLC	INTUITIVE SURGICAL, DA VINCI ROBOT - EMAILS, LETTERS TO OR FROM FDA RE SAFETY, COMPLICATIONS, ADVERSE EVENTS; PHYSICIANS, HOSPITALS WHO WERE SENT A SURVEY IN 2012 OR 2013 RE DA VIN CI ROBOT PRODUCT SAFETY ISSUES (09/30/12-03/01/2013)
2013-1626	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mario A. Inchiosa, Jr., Ph.D. NEW YORK MEDICAL COLLEGE	PHENOXYBENZAMINE - AERS
2013-1627	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Jasmine Bager Columbia Journalism School	FIVE HOUR ENERGY DRINK - FOIA REQUESTS (03/01/2000 - 03/01/2013)
2013-1628	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123845
2013-1629	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	K090312
2013-1630	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	INVERNESS MEDICAL, INVERNESS, SCOTLAND - EIR PAGES 5 TO 7; 483 PAGES 1 TO 2 (04/19/04-4/22/04)
2013-1631	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120737
2013-1632	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122280
2013-1633	03/04/2013 04/01/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Elaine Noblit United Therapeutics Corporation	ROBYN J BARST, NEW YORK, NY - EIR 02/02/01; ROBERT C BOURGE, BIRMINGHAM, AL - EIR 01/08/01; ADAANI E FROST, HOUSTON, TX - EIR 01/18/01
2013-1634	03/04/2013 04/01/2013	FDA/OF/CFSSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Murray Carpenter Murray Carpenter	12/05/12 MTG BETWEEN MICHAEL LANDA AND HYMAN, PHELPS, MCNAMARA, INTERTEK CONTOX, RE ENERGY DRINKS - MINUTES; CORR; ROCKSTAR CORR WITH FDA AFTER 05/12 WARNING LETTER
2013-1635	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110301
2013-1636	03/04/2013 04/01/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA GROUP INC	HHSF223200850014I ORDER 3 HHS0001 - CONTRACT, MODIFICATIONS

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2013-1637	03/04/2013 04/17/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF223201110030I
2013-1638	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-171 REQUEST LETTER
2013-1639	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-497 REQUEST LETTER
2013-1640	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-547 REQUEST LETTER
2013-1641	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 2/1/2013 - 3/1/2013
2013-1642	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-620 REQUEST LETTER
2013-1643	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 02/01/13-02/28/2013
2013-1644	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-89 REQUEST LETTER
2013-1645	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-692 REQUEST LETTER
2013-1646	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-298 REQUEST LETTER
2013-1647	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-351 - REQUEST LETTER
2013-1648	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-132 REQUEST LETTER
2013-1649	03/04/2013 04/01/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JASON A FORGE ROBBINS GELLER ET AL	USA V SCOTTS MIRACLE-GRO CO - INVESTIGATION RECS, RPTS, MEMOS, ETC
2013-1650	03/04/2013 04/01/2013	CVM/OCD/	Nathan Bahill Stetson University School of Law	GENETICALLY ALTERED ATLANTIC SALMON - LIST OF STUDIES AND DATA RE MIXING, BREEDING WITH WILD OR NATURAL ALTANTIC SALMON
2013-1651	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSHUA M GLASSER ARNOLD & PORTER	ERIVEDGE (VISMODEGIB) CAPS NDA 20-3388 - APRVL LTR 1/30/12
2013-1652	03/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID W GERDT PHD	TL-300 T-LINE K123446, NEXFIN M ODE 1014 K072049, CC

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	04/01/2013	FDA/OC/OES/DFOI/	EMPIRICAL T ECHNOLOGIES CORP	NEXFIN K101123, ETC
2013-1653	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAURA HOBBS LEXISNEXIS COURTLINK INC	NORAMCO, RHODES TECHNOLOGIES, MALLINCKRODT/COVIDIEN, ETC - 14-HYDROXYCODEINONE RESP, SUBMISSIONS, CORR, ETC
2013-1654	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/OMP/DODM/	ELIZABETH MOCCALDI BUTLER, SNOW, O'MARA, STEVENS & CANNADA, PLLC ATTORNEYS AT LAW	PROSCAR, PROPECIA - CITIZEN PETITIONS
2013-1655	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANOSHIMA MD HOSPITAL FOR SICK CHILDREN	COPAXONE (GLATIRAMER ACETATE) - ISRS 6868065, 6853352, 7236316, ETC
2013-1656	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F GORDON DVM CLINREG CONSULTING SERVICES INC	CIBA VISION - K073459
2013-1657	03/04/2013 08/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	LEIGH SANDERS CENTER FOR RESPONSIBLE SCIENCE	ANIMAL TESTING - INTERNAL ANALYSIS, TRADE SECRETS, PATENTS, ETC
2013-1658	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TYRAH L MILES DJA GLOBAL PHARMACEUTICALS INC	OSPHENA (OSPENIFENE) - SBA
2013-1659	03/04/2013 04/01/2013	FDA/OGROP/ORAN-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-1660	03/04/2013 04/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MARC RENDELL MD ASNDI	NOVO NORDISK - INSULIN DEGLUDEC APRVL RLECS, INVESTIGATION, A/C MTG

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		OM/OMP/DODM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1661	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROSETTE, FRANK	GRISEOFULVIN - AERS
2013-1662	03/04/2013 04/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS - VAERS
2013-1663	03/04/2013 04/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLO CASULO MD ASCEND CAPITAL LLC	STRIDE ARCO LABS - 483, WARNING LTRS, CLOSE OUT LTRS 1/1/10 TO 2/27/13
2013-1664	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARBARA J WHITMAN INTEGRA LIFESCIENCES CORP	INTEGRA LIFESCIENCES CORP - COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT P810006/S002
2013-1665	03/04/2013 04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARBARA J WHITMAN INTEGRA LIFESCIENCES CORP	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE P850010/S005
2013-1666	03/04/2013 04/01/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 161330
2013-1667	03/04/2013 04/01/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 155879, 157049, 161089
2013-1668	03/04/2013 04/01/2013	FDA/OC/OES/DFOI/ ORA/ ORA/	Smith, Shari D	NECC 4/16/02 INSPECTION - EXHIBITS
2013-1669	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kelly Jabbal AccessClosure, Inc.	P930038 S052
2013-1670	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Carroll BRINKS HOFER GILSON & LIONE	US PATENT 8,372,872 - ORANGE BOOK SUBMISSION

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1671	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125118 S122
2013-1672	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	1 Rosales, Ruth R	COLISTIN - CLINICAL STUDIES
2013-1673	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jane Keathley Keathley and Company LLC	K113853
2013-1674	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maninder Chopra Kirax Corp	HYDROCODONE, HYDORCODONE/ACETAMINOPHEN - NDA RECS
2013-1675	03/05/2013 04/02/2013	FDA/OF/CFSAN/OCDE/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	TADIN CORP - CORR, COMM WITH FDA (12/28/2008 - 03/04/2013)
2013-1676	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103795 S 5110
2013-1677	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	C J Pillar CJP Consulting, Inc.	K120135
2013-1678	03/05/2013 04/02/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	SIMILASAN - CORR, COMM WITH FDA (1/01/2003 - 03/04/2013)

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2013-1679	03/05/2013 04/02/2013	FDA/OF/CFSAN/OCD/EOS/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	IOVATE - CORR, COMM WITH FDA
2013-1680	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Wayne Thuna FMC Distributors, Inc.	FMC DISTRIBUTORS, INC, PONCE, PR - EIR (12/08/2009 - 12/11/2009)
2013-1681	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	VIVELLE DOT - AERS
2013-1682	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Joseph Anderson Joseph Anderson	DR MICHAEL RING - EIR AUGUST 2012
2013-1683	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20812
2013-1684	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20812 S007, 011
2013-1685	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 20267
2013-1686	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20267, S005
2013-1687	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	QILU PHARMACEUTICAL, JINAN, CHINA - EIR, 483, WARNING LETTER, ETC (06/28/2010-07/01/2010)
2013-1688	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Leon Neumedicines Inc.	G-CSF (NEUPOGEN) - EMERGENCY USE AUTHORIZATION APPLICATIONS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1689	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Leon Neumedicines Inc.	CYTOKINES - IND, EMERGENCY USE AUTHORIZATIONS
2013-1690	03/05/2013 04/02/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANGELA E MCGRAW FLEISHMAN & SHAPIRO PC	MERCK & CO INC - INVANZ RECALL RECS
2013-1691	03/05/2013 04/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN NICPON CMP INDUSTRIES LLC	DURAFLEX K063626
2013-1692	03/05/2013 04/02/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COREY B RUBENSTEIN STETLER DUFFY & ROTERT LTD	TOTAL NUMBER OF INVESTIGATIONAL NEW DRUG APPLICATIONS (INDA) FILED, CLNCL HOLDS FOR CBER AND CDER 2007 TO 2010, ETC
2013-1693	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIA MATTERN GLAXO SMITH KLINE	FINASTERIDE - ISRS 3055449-9, 3076713-3, 3505197-3, ETC
2013-1694	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	SEPTOCAINE INJ, ARTICAINE HCL - ISRS 8480724, 8529551, 8530048, ETC
2013-1695	03/05/2013 04/02/2013	FDA/OF/CFSAN/OCD/EOS/	LISA P ALSOBROOK Keller and Heckman LLP	CHITEC TECHNOLOGY CO LTD, HANSON GROUP LLC - FCN 537, FCN 935 CHEMISTRY & TOXICOLOGY MEMOS
2013-1696	03/05/2013 04/02/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SAMUEL F COLIN MD FIRST MANHATTAN CO	LUITPOLD PHARMACEUTICALS INC - 483S, WARNING LTRS, CO RESP 2/1/13 TO PRESENT
2013-1697	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	MICHAEL CODY APHENA PHARMA SOLUTIONS	BLU CARIBE INC, DORADO, PR - EIR 10/12
2013-1698	03/05/2013	FDA/OF/CFSAN/OCD/EOS/	DAVID C STEINBERG	HAIR STRAIGHTENER COSMETICS REGISTERED WITH FDA

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	04/02/2013		STEINBERG & ASSOCIATES INC	UNDER VCRP BASED ON THIOGLYCOLIC ACID, SALTS, ESTERS - CAERS 2000 TO PRESENT
2013-1699	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TOM BURTON WALL STREET JOURNAL	OMONTYS (PEGINESATIDE) - AERS
2013-1700	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	HOSPIRA COSTA RICA LTD, LA AURORA de HEREDIA - EIR, 483, CO RESP 4/12
2013-1701	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	XYLO CHEM INDUSTRIES, NADIAD, INDIA - EIR, 483, CO RESP 6/11
2013-1702	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	BULK MEDICINES & PHARMACEUTICALS GMBH, NORDERSTEDT, GERMANY - EIR, 483, CO RESP 11/11
2013-1703	03/05/2013 04/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	COREPHARMA LLC - EIR, 483, CO RESP 6/12
2013-1704	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	NOVO NORDISK AS, BAGSVAERD, DENMARK - EIR, 483, CO RESP 3/12-20/12
2013-1705	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	BEANNE CHEMICAL CO, TAICHUNG CITY , TAIWAN - EIR, 483, CO RESP 5/2-4/12
2013-1706	03/05/2013 04/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PA BENJAMIN MAUFACTURING CO LTD, KINGSTON, JAMAICA - EIR, 483, CO RESP 5/5-11/12

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2013-1707	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SINGING RIVER HEALTH SYS IRB, PASCAGOULA, MS - EIR, 483, CO RESP 7/2-23/12
2013-1708	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ADVANCED SPECIALTY PHARMACY, BESSEMER, AL - EIR, 483, CO RESP 3/23-25/11
2013-1709	03/05/2013 05/07/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SOVEREIGN PHARMACEUTICALS LLC, ST FORT WORTH, TX - EIR, 483, CO RESP - 1/18 TO 2/2/12
2013-1710	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	THE AMERICAN NATIONAL RED CROSS, DOUGLASVILLE, GA - EIR, 483, CO RESP 6/12
2013-1711	03/05/2013 04/02/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CHI RHO CLIN INC - BURTONSVILLE, MD - EIR, 483, CO RESP 4/12
2013-1712	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CRESENDO THERAPEUTICS LLC, VISTA, CA - EIR, 483, CO RESP 1/12
2013-1713	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, CLEVELAND MS - EIR, 483, CO RESP 6/12
2013-1714	03/05/2013 04/02/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	NORTHERN INDIANA CANCER RESEARCH CONSORTIUM IRB, SOUTH BEND IN - EIR, 483, CO RESP 2/12
2013-1715	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	STAT RX USA, GAINESVILLE, CA - EIR, 483, CO RESP 2/12
2013-1716	03/05/2013 04/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	GENERITECH CORP, FRESNO, CA - EIR, 483, CO RESP 4/12
2013-1717	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	APPLIED CONSUMER SERVICES INC, HILEAH GARDENS, FL - EIR, 483, CO RESP 1/12
2013-1718	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E. CHALKLEY THOMSON REUTERS	HILL DERMACEUTICALS INC, SANDFORD, FL - EIR, 483, CO RESP 3/12
2013-1719	03/05/2013 04/02/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HEMARUS LLC, JACKSONVILLE, FL - EIR, 483, CO RESP 3/12
2013-1720	03/05/2013 04/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	COREPHARMA LL, MIDDLESEX, NJ - EIR, 483, CO RESP 2/11
2013-1721	03/05/2013 04/02/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	HOSPIRA, LAKE FOREST, IL - EIR, 483, CO RESP 1/13

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2013-1722	03/05/2013 04/02/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ABBEY COLOR INC, PHILADELPHIA, PA - EIR, 483, CO RESP 3/13-23/12
2013-1723	03/05/2013 04/02/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MICHAEL E. RING MD, SPOKANE, WA - EIR, 483, CO RESP 8/23/12
2013-1724	03/05/2013 04/02/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MARK PINSKY MD, PALM BEACH GARDENS, FL - EIR, 483, CO RESP 9/17-28/12
2013-1725	03/05/2013 04/02/2013	CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	ANHYDROUS AMMONIA - CATTLE FOOD ADDITIVE PETITION CORR, RVWS, APRVL
2013-1726	03/05/2013 04/02/2013	CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	ANHYDROUS AMMONIA - FOOD ADDITIVE PETITION MF 3673 CORR, RVW, APRVL
2013-1727	03/05/2013 04/02/2013	CVM/OCD/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	ANHYDROUS AMMONIA - DAIRY FOOD ADDITIVE PETITION MF 3555 CORR, RVWS, APRVL
2013-1728	03/05/2013 04/02/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MANUFACTURING, BIORESEARCH MONITORING - INSP 1/13
2013-1729	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Peter Gallagher ZBI	VALEANT PHARMACEUTICALS - COMPLAINTS RE SAFETY, MARKETING, GMP COMPLIANCE (03/01/2008 - 03/01/2013)
2013-1730	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7350
2013-1731	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-1919
2013-1732	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8176
2013-1733	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-5493
2013-1734	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4172
2013-1735	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7572
2013-1736	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	VILDAGLIPTON - PEDIATRIC WRITTEN REQUEST FOR STUDIES

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1737	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Jim McNair Jim McNair	FDA RESPONSE TO MAUDE REPORT
2013-1738	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ Jim McNair	Jim McNair	FDA RESPONSE TO MAUDE REPORT
2013-1739	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tang S. Peng ChemWerth, Inc.	MICROTROL STERILIZATION SERVICES PVT LTD, KARNATAKA, INDIA - EIR
2013-1740	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	APLISOL - AERS (03/05/2010 - 03/05/2013)
2013-1741	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Catherine Bowen Barclays Research	HOSPIRA - 483 (02/25/2013 - 03/04/2013)
2013-1742	03/07/2013 04/04/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jim McNair Jim McNair	DA VINCI ROBOTIC SURGICAL SYSTEM - LETTERS, MEMOS, REPORTS RE SAFETY CONCERNS
2013-1743	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AVANDIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1744	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	NASONEX 50 MCG - AERS
2013-1745	03/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tycho Peterson	INTUITIVE SURGICAL, DA VINCI SURGERY - COMM BTWN FDA AND HOSPITALS, PHYSICIANS AS PART OF MEDSUN

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	04/04/2013		J.P. Morgan Securities LLC	FROM 1/2006 TO PRESENT; SURVEY RECS
2013-1746	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	QILU, JINAN, CHINA - EIR, WARNING LETTER, COMPANY RESPONSE ETC (06/28/2010 - 07/01/2010)
2013-1747	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AVANDIA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1748	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	TRAJENTA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1749	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ONGLYZA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1750	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lakshmi Raghavan DermPathe Pharmaceuticals	ZOVIRAX OINTMENT - OPEN MANUFACTURING PROCESS IN NDA
2013-1751	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	David Mangione Govzilla, Inc.	CATALENT PHARMA SOLUTIONS LLC, MORRISVILLE, NC - 483 (02/14/2013 - 02/14/2013)
2013-1752	03/07/2013 04/04/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky KOWINSKY, BARBARA	THIBIANT LABORATORIES, CHATSWORTH, CA - EIR, WARNING LETTER, VIOLATIONS (01/03/2011 - 03/30/2012)
2013-1753	03/07/2013 04/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	AVANDAMENT - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1754	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Jessica Fye J.P. Morgan Securities LLC	HOSPIRA, ROCKY MOUNT, NC - 483 (02/01/2013 - 03/05/2013)
2013-1755	03/07/2013 04/04/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS FEB 2013

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2013-1756	03/07/2013 04/04/2013	FDA/OC/OES/DFOI/	Johnathan Rickman FDANEWS	FOIA REQUEST LOG (02/25/2013 - 03/01/2013)
2013-1757	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jim McNair Jim McNair	FDA CONCERNS ABOUT DA VINCI SURGICAL SYSTEM SAFETY
2013-1758	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hana Camarillo Pacific University School of Pharmacy	XARELTO - POSTMARKETING SAFETY DATA FOR TWO NEW INDICATIONS
2013-1759	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	KOMBIGLYZE - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1760	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JANUMET - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1761	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Chris Kuehnle LEERINK SWANN & CO	HOSPIRA, ROCKY MOUNT, NC - 483 (02/28/2013 - 03/06/2013)
2013-1762	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JENTADUETA - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1763	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	JUVISYNC - PEDIATRIC WRITTEN REQUEST FOR STUDIES
2013-1764	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Michael Marini Capsugel Inc.	CAPSUGEL INC, GREENWOOD, SC - EIR (06/21/2011 - 12/31/2011)
2013-1765	03/07/2013 04/04/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Tom East Tom East Consulting	IMPAX LABORATORIES, HAYWARD, CA - 483 (01/07/2013 - 03/05/2013)
2013-1766	03/07/2013 04/04/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Shibani Malhotra RBC CAPITAL MARKETS	HOSPIRA, ROCKY MOUNT, NC - (03/01/2013 - 03/06/2013)
2013-1767	03/07/2013	FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton	AVANDARYL - PEDIATRIC WRITTEN REQUEST FOR

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	04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	INC RESEARCH CONSULTING & SUBMISSIONS	STUDIES
2013-1768	03/07/2013 04/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OM/OMP/DDM/	Bethany Farmer INFOTRIEVE	PRESENTATION OF EFFICACY RESULTS OF SINGLE-DOSE ANALGESICS FOR STUIES USING ACUTE PAIN MODELS
2013-1769	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joyce Dobervich Estill Medical Technologies, Inc.	K012031
2013-1770	03/07/2013 04/04/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Mark Prinz Registrar Corp	ENTRY NUMBER DO7-8403124-0
2013-1771	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121216
2013-1772	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102788
2013-1773	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071187
2013-1774	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K010051
2013-1775	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K002172
2013-1776	03/07/2013 04/04/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Christine James Sound Sleep Health	HCG FOR WEIGHT LOSS - AERS (01/01/2000 - 02/28/2013)
2013-1777	03/07/2013 04/04/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	MOD-423 ORPHAN DESIGNATION
2013-1778	03/07/2013 04/04/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Brian Brown Carlson, Gaskey & Olds	ANSAR GROUP, PHILADELPHIA, PA - WARNING LETTER RECS, INVESTIGATION (01/01/2010 - 03/06/2013)

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2013-1779	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093799
2013-1780	03/07/2013 04/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ellen Zimmerman ClearView Diagnostics In.	K080935
2013-1781	03/07/2013 04/04/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Pinar Cakir EKIN KIMYA TIC. LTS. STI.	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR 12/2010
2013-1782	03/07/2013 04/04/2013	FDA/OF/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps and McNamara	COFFEE BEVERAGES - CAERS (01/01/2004 - 10/23/2012)
2013-1783	03/07/2013 05/30/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	David Mangione Govzilla, Inc.	PFIZER, PEARL RIVER, NY; HOSPIRA, ROCKY MOUNT, NC; CRUCELL, BERNE, SWITZERLAND, ETC - INSPECTION RECS
2013-1784	03/08/2013 04/05/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Daniel Kantor Daniel Kantor	GILENYA - AERS
2013-1785	03/08/2013 04/05/2013	FDA/OF/CFSAN/OCD/EOS/	Daniel Tokar Pinnacle Foods LLC	TROPIJUGOS, SA, SANTO DOMINGO, DR - EIR, 483 (02/01/2013 - 03/01/2013)
2013-1786	03/08/2013 04/05/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	HERBALIFE - AERS
2013-1787	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	HERBALIFE - EIR, 483 FROM LOS, SAN, ATL (01/01/2003)

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		FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/		
2013-1788	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Yigal Nochomovitz Morgan Stanley	HOSPIRA, ROCKY MOUNT, NC - 483 (02/12/2013 - 03/01/2013)
2013-1789	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Gregoire ALGORITHM PHARMA INC	PHARMANET CANANDA, QUEBEC, CANADA; PHARMA MEDICA RESEARCH INC MISSISSAUGA, CANADA; PRACS INSTITUTE LTD, S FARGO, ND ETC - 483 (01/01/10)
2013-1790	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FARAH JAVID-MAJD University of Houston College of Pharmac	IV ZOLEDRONIC ACID, PAMIDRONATE - MEDWATCH RECS
2013-1791	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Hermelin Xeragenx LLC	NDA 016635, ANDA 084264, NDA 016635 ETC
2013-1792	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	Pam Williams Williams, Pam	HOSPIRA - 483, WARNING LETTERS (01/03/2011 - 03/29/2013)
2013-1793	03/08/2013 04/05/2013	ORA/OE/ ORA/OE/	Kaitlin Wowak UNIVERSITY OF NOTRE DAME	RECALL DATA SPREADSHEETS (01/01/2004 - 03/07/2013)
2013-1794	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Leo Trevino Liquidia Technologies, Inc.	XALATAN - SBA
2013-1795	03/08/2013	FDA/OGROP/ORA/CE-FO/DET-	Ed Silverman	PFIZER, TERRE HAUTE, IN - 483 (01/03/2012 - 12/31/2013)

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	04/05/2013	DO/DET-CB/	PHARMALOT	
2013-1796	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dustin Block IPD ANALYTICS LLC	ANDA 090999 - EFFECTIVE APPROVAL LETTER
2013-1797	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K770717
2013-1798	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	LEO PHARMA AS - DOVONEX (CALCIPOTRIENE) CREAM NDA 20-554 SBA
2013-1799	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	ARMOUR, STEPHANIE	SALMONELLA, E COLI, LISTERIA OUTBREAKS ASSOCIATED WITH RESTAURANTS, RETAILERS, FARMS 2009 TO 7/6/12
2013-1800	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN G BERGMAN HELSELL FETTERMAN LLP	GLAXOSMITHKLINE - LAMICTAL TABS NDA 20-241 APRVL LTR, RVWS, LBLG, ETC
2013-1801	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/ ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	TONY CORBO Food & Water Watch	KASEL ASSOCIATED INDUSTRIES INC, DENVER. CO - INSPS, PROD TESTING 2/13
2013-1802	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRANZ MENEAN MEDAGENT INC	K112121 - LBLG, INSTRUCTIONS FOR USE, IFU STATEMENTS
2013-1803	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	STEVE STROUPHAUER BD LEE LABS	LEE LABS, GRAYSON, GA - EIR 9/6-28/07

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2013-1804	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ROMAN ROZENFELD POINTSTATE CAPITAL LP	HOSPIRA, ROCKY MOUNT - 483 2/13
2013-1805	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENENTECH INC - EIR, 483, CO RESP 8/12
2013-1806	03/08/2013 04/05/2013	FDA/OF/CFSAN/OCD/EOS/	DEENA KALAI PLLC	CHANEL, LANCOME, CLINIQUE, ETC - COSMETIC PROD INGREDIENT STATEMENTS
2013-1807	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARC RENDELL MD ASNDI	NOVO NORDISK - INSULIN DEGLUDEC APRVL RECS
2013-1808	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 2/1-28/13
2013-1809	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	CHARLIE NETTLETON HEALTHCOR MANAGEMENT LP	HOSPIRA INC - EIRS, 483S, UNTITLED LTRS, ETC 3/1/10 TO 3/1/13
2013-1810	03/08/2013 04/05/2013	CVM/OCD/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	NATIONAL COTTONSEED PRODUCTS ASSN - FAP 2172
2013-1811	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMPSON JR, THOMAS W	DENTAL FLOSS - CLNCL TESTINGS, STANDARDS, CLASSIFICATION, ETC
2013-1812	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE S RICHARD INDAGO GROUP	INTUITIVE SURGICAL INC, SUNNYVALE, CA - DA VINCI ROBOTIC SURGERY SYS SAFETY, MDRS, TRAINING RECS
2013-1813	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S WALLER PHARM D MBA SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - ISRS 8454532, 8486800, 8621754, ETC
2013-1814	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	MARGARET M GROVES JD DUKE UNIV/SCHOOL OF MEDICINE	KIMBERLY BLACKWELL MD, DUKE UNIV MEDICAL CTR, DURHAM, NC - EIR, CLOSE OUT LTR 6/5-7/12
2013-1815	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	MARGARET MGROVES JD DUKE UNIV/SCHOOL OF	SARAH H LISANDBY MD, DUKE UNIV MEDICAL CTR, DURHAM, NC - EIR 10/11-129/12

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			MEDICINE	
2013-1816	03/08/2013 04/05/2013	ORA/ ORA/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	CENTRAL ADMIXTURE PHARMCY SERVICES INC, CHICAGO, IL - EIRS 1/1/10 TO PRESENT
2013-1817	03/08/2013 04/24/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OC/OES/DFOI/	CAHRLES CELESTE EAS CONSULTING GROUP LLC	NOVARTIS VACCINES & DIAGNOSTICS, EMERYVILLE, CA - EIR 5/12
2013-1818	03/08/2013 04/05/2013	ORA/ ORA/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	WEDGEWOOD PHARMACY, SWEDESBORO, NJ - EIRS 1/1/10 TO PRESENT
2013-1819	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORASURE TECHNOLOGIES, BETHLEHEM, PA - 483, EIR, CO RESP, WARNING LTR 1/03 TO PRESENT
2013-1820	03/08/2013 04/05/2013	ORA/ ORA/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	APOTHECURE INC, SALLAS, TX - EIRS 1/1/10 TO PRESENT
2013-1821	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	TONY HURTADO Liberty Mutual Fire Insurance Company	NATIONAL MARKETING LLC, ANAHEIM, CA - ESTABLISHMENT REGISTRATION, LICENSING RECS, CORR, ETC
2013-1822	03/08/2013 04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	TONY HURTADO Liberty Mutual Fire Insurance Company	ASPEN MEDICAL RESOURCES LLC, ANAHEIM, CA - ESTABLISHMENT REGISTRATION, LICENSING RECS, CORR, ETC
2013-1823	03/08/2013 04/15/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	SIEMENS HEALTH CARE DIAGNOSTICS INC, TARRYTOWN, NY - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1824	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	SIEMENS HEALTHCARE DIAGNOSTICS INC, BERKELEY, CA - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1825	03/08/2013 04/05/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORTHO CLINICAL DIAGNOSTICS INC, ROCHESTER, NY - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1826	03/08/2013 08/08/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ORTHO CLINICAL DIAGNOSTICS INC, RARITAN, NJ - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1827	03/08/2013 04/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT LABS POINT OF CARE, PRINCETON, NJ - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1828	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT DIAGNOSTICS, LAKE FOREST, IL - 483, EIR, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1829	03/08/2013 04/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT, WIESBADEN, GERMANY - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT

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2013-1830	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT MOLECULAR, DES PLAINES, IL - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1831	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OC/OES/DFOI/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT LABS, ABBOTT PARK, IL - EIR, 483, WARNING LTR, CO RESP 1/03 TO PRESENT
2013-1832	03/08/2013 04/05/2013	CVM/OCD/	Scott Krygier BASF Corp.	FORMIC ACID, FORMATE - ANIMAL SAFETY STUDIES
2013-1833	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Michael Rich Raymond James & Associates	HOSPIRA, ROCKY MOUNT, NC - 483 (03/01/2013 - 03/08/2013)
2013-1834	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	STEVE RITTKE BALYASNY ASSET MANAGEMENT	ST JUDE MEDICAL, SYLMAR, CA - 483 1/12 TO 3/5/13
2013-1835	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	STEVE RETTKE BALYASNY ASSET MANAGEMENT	HOSPIRA INC, ROCKY MOUNT, NC - 483 1/12 TO 3/5/13
2013-1836	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	STEVE RETTKE BALYASNY ASSET MANAGEMENT	IMPAX LABS, HAYWARD, CA - 483 1/12 TO 3/5/13
2013-1837	03/08/2013 04/05/2013	ORA/ ORA/	JOHN MARK ZINI GIDEON COOPER & ESSARY	PHARMEDIUM LLC, LAKE FOREST, IL - EIR SINCE 1/10
2013-1838	03/08/2013 04/05/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	JOHN MARK ZINI GIDEON COOPER & ESSARY	PHARMACIA UPJOHN, KALAMAZOO, MI - EIR 2002
2013-1839	03/08/2013 04/05/2013	ORA/ ORA/	JOHN-MARK ZINI GIDEON COOPER & ESSARY	LEE SILSBY COMPOUNDING PHARMACY , CLEVELAND HEIGHTS, OH - EIR SINCE 1/10
2013-1840	03/08/2013 04/05/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	MANOJ K. GARG HEALTHCO	HOSPIRA, ROCKY MOUNT, NC - 483 3/1/13
2013-1841	03/08/2013 04/05/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	CYNTHIA PATINO LEWIS BRISBOIS ET AL	POMONA VALLEY HOSPITAL CTR - INSP, CMLPLNTS, CORR 2002 TO PRESENT
2013-1842	03/08/2013 04/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BETH RYAN LOMMEN ABDO COLE KING STAGEBERG PA	INDIVIDUAL RECS
2013-1843	03/08/2013 04/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZANNE KETTERIDGE NEW HAMPSHIRE PUBLIC	FETANYL PATCHES - AER 1997 TO 2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DEFENDER	
2013-1844	03/08/2013 04/05/2013	FDA/OC/OES/DFOI/	WENEEKE, HURLEY	GENERIC DRUG APPLICATIONS & DENIALS
2013-1845	03/11/2013 04/08/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Cheryl CONSUMER	ZI XIU TANG BEE POLLEN - MANUFACTURER
2013-1846	03/11/2013 04/08/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURE'S INNOVATION, INC - CORR, COMM WITH FDA (12/19/2008 - 03/06/2013)
2013-1847	03/11/2013 04/08/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	HEEL, INC. - CORR, COMM WITH FDA
2013-1848	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Walter Cordiglia ReflexionHealth, Inc	K943430
2013-1849	03/11/2013 04/08/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	DIAL CORPORATION - CORR, COMM WITH FDA (01/01/2009 - 03/06/2013)
2013-1850	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Del Stringham Stringham, Del J	LEVOTHRYOXINE - IN VIVO BIOAVAILABILITY DATA, TABLET DISSOLUTION DATA
2013-1851	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert Langreth BLOOMBERG NEWS	INTUITIVE SURGICAL DA VINCI SURGICAL SYSTEM - CORR, EMAILS, RECS RE APPROVAL, CLEARANCE

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		FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/		
2013-1852	03/11/2013 04/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Kasie Davis Davis, Kasie L	COVENANT HEALTH SYSTEM, LUBBOCK, TX - DEATHS (01/01/2009 - 12/31/2011)
2013-1853	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Keyser Keyser, Andrew L	AMBIEN - EFFECTIVE DOSE, CONCENTRATION , STUDIES
2013-1854	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K903205, K914190, K801589 ETC
2013-1855	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K823351
2013-1856	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K110824
2013-1857	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K983393, K896919, K003819
2013-1858	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K970481, K955628, K955854 ETC
2013-1859	03/11/2013 04/08/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Jessica Wong GENERAL MILLS	GENERAL MILLS, WEST CHICAGO, IL; GENERAL MILLS, MUFREESBORO, TN; GENERAL MILLS, BELVIDERE, IL; ETC - EIR, 483, RESPONSE
2013-1860	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thuc Quyen Nguyen Thuc Quyen Nguyen	SUMATRIPTAN - AERS
2013-1861	03/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JD Webb	K112736

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	04/08/2013		The OrthoMedix Group, Inc.	
2013-1862	03/11/2013	OC/OOPD/	Faryal Hasan	COLCHINE - ORPHAN DRUG DESIGNATION RECS
	04/08/2013	FDA/OMPT/OSMP/OOPD/	Hyman, Phelps & McNamara, P.C.	
2013-1863	03/11/2013	FDA/OF/CFSAN/OCDEOS/	Law Offices of Ronald A. Marron	NATURAL BALANCE, NUTRACEUTICAL - COMM, CORR
	04/08/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Law Offices of Ronald A. Marron	WITH FDA(1/01/2006 - 03/08/2013)
2013-1864	03/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh	K872235, K860540, K803676
	04/08/2013		Framingham Heart Study	
2013-1865	03/11/2013	FDA/OMPT/CDER/ERP/DIDP/	Alan S. Ryan, PhD	FLUOGUM - SBA
	04/08/2013	FDA/OMPT/CDER/ERP/DIDP/	Sancilio and Company, Inc.	
		FDA/OMPT/CDER/ERP/DIDP/		
		FDA/OMPT/CDER/ERP/DIDP/		
2013-1866	03/11/2013	FDA/OC/OES/DFOI/		ARICEPT - RECS
	04/08/2013		GREENBERG, K BEN	
2013-1867	03/11/2013	FDA/OMPT/CDER/ERP/DIDP/		INDIVIDUAL RECS
	04/08/2013	FDA/OMPT/CDER/ERP/DIDP/	Doe J	
		FDA/OMPT/CDER/ERP/DIDP/		
		FDA/OMPT/CDER/ERP/DIDP/		
2013-1868	03/11/2013	ORA/	CHRISTOPHER M KANE	FOOD AND SWEETS TRADING GMBH, OESCHGEN,
	04/08/2013	ORA/	SIMON GLUCK & KANE LLP	SWITZERLAND - INSPECTOR NOTES, EMAILS, LAB
		FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		RESULTS, ETC
2013-1869	03/11/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	PETER J SOMERA JR	STRYKER - NEPTUNE S ULTRA WASTE MANAGEMENT SYS
	04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SOMERA & SILVA LLP	MDRS, RECALLS, APRVLS, ETC
		FDA/OC/OES/DFOI/		
2013-1870	03/11/2013	FDA/OF/CFSAN/OCDEOS/	MICHAEL J VILLEGGIANTE ESQ	MOON MARINE CORP, MOON FISHERY PVT LTD, OCEAN
	04/08/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WELTIN STREB & WELTIN	QUEEN SEAFOOD INC, ETC - SALMONELLA OUTBREAK
		FDA/OGROP/ORA/ORO/DIOP/		INVESTIGATION RECS, CORR 2012
2013-1871	03/11/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	K MICHELLE VASSALLO	RX STAT INC, FL - EIRS, 483S, WARNING LTRS 1/1/05 TO
	04/08/2013		LINCARE INC	PRESENT
2013-1872	03/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROGER SONNENBURG	MILES LABS - K831600
	04/08/2013		BAYER HEALTHCARE LLC	

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2013-1873	03/11/2013 04/08/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	VICTOR GREEN KCAS LLC	KCAS LLC, SHAWNEE, KS - EIR 7/18-22/11
2013-1874	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WENDY JO ROGERS CORSON & JOHNSON LAW FIRM	AMIODARONE - AERS 1/1/01 TO PRESENT
2013-1875	03/11/2013 04/08/2013	FDA/OO/OHR/	JOCELYN SKINNER ESQ HOUSE OF RUTH MARYLAND INC	INDIVIDUAL RECS
2013-1876	03/11/2013 04/08/2013	FDA/OF/CFSAN/OCD/EOS/	MICHELLE LEVINSON NATURAL RESOURCES DEFENSE COUNCIL	PRIORITY BASED ASSESSMENT OF FOOD ADDITIVE DATABASE (PAFA)
2013-1877	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	CASES OF CHOCOLATES SMLU3281673 - RECS
2013-1878	03/11/2013 04/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	CASES OF CHOCOLATES SMLU3135013A - RECS
2013-1879	03/11/2013 04/08/2013	FDA/OF/CFSAN/OCD/EOS/	GREENBERG, BEATRICE	CORN REFINERS ASSN, WASHINGTON, DC - CORR REGARDING USE OF THE TERM NATURAL TO DESCRIBE HIGH FRUCTOSE CORN SYRUP
2013-1880	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	ORTHO0CLINICAL DIAGNOSTICS INC/JOHNSON & JOHNSON, WYCOMBE, BUCKINGHAMSHIRE, UK - EIRS, 483S, WARNING LTRS, ETC 1/103 TO PRESENT
2013-1881	03/11/2013 04/08/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	ABBOTT LABS, ABBOTT PARK, IL - EIRS, 483S, WARNING LTRS, ETC 1/03 TO PRESENT
2013-1882	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SCOTT A HANNA ZUCKERMAN SPAEDER LLP	IRON-O-VITA NDA 01-885, VITABLE NDA 01-285 - APRVL RECS
2013-1883	03/11/2013 04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARK A KOPEC HABCO INDUSTRIES LLC	PACIFIC PRECISION PRODUCTS - PORTABLE OXYGEN GENERATOR K120566
2013-1884	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	JUBILANT HOLLISTER STIER, QUEBEC, CANADA - 483 3/19-26/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-1885	03/11/2013 04/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	JUBILANT HOLLISTER STIER, QUEBEC, CANADA - EIR 3/19-26/12
2013-1886	03/11/2013 04/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MUJIB U QIDWAI GRIFOLS BIOLOGICALS INC	OCTAPharma AB, STOCKHOLM, SWEDEN - EIR, 483 1/10-20/11
2013-1887	03/11/2013 04/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MUJIB U QIDWAI GRIFOLS BIOLOGICALS INC	CSL BEHRING, VICTORIA, AUSTRALIA - EIRS, 483S 1/10 TO 12/12
2013-1888	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	ROSS RENDELMANN HOGAN LOVELLS LLP	DKT FDA-2013-P-0070, FDA-2012-P-1103
2013-1889	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058
2013-1890	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-2012-S-1178, FDA-199-S-0039
2013-1891	03/11/2013 04/08/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT FDA-2012-P-0904
2013-1892	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Neely Kinamed Incorporated	K102834, K013982, K072250 ETC
2013-1893	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeanne Truitt Smiths-Medical	DRUG FOR TISSUE DAMAGE, EXTRAVASATION - AERS
2013-1894	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMANTADINE - AERS
2013-1895	03/12/2013 04/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Doe J	ORTHO DIAGNOSTIC SYSTEMS, RARITAN, NY - EIR, AERS
2013-1896	03/12/2013 04/09/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/	Brent Arbogast Critical Process Filtration	AGRIFLU - 483, COMPARABILITY STUDY, ETC (07/10/2008 - 03/08/2013)

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		ALFB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/		
2013-1897	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Juha-Pekka Nuutinen Mectalent Medical Services	K053225
2013-1898	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	FLECTOR - PATENT TERM EXTENSION CORR
2013-1899	03/12/2013 04/09/2013	FDA/OF/CFSAN/OCD/EOS/	Douglas Barasatian citizens petition	BLEACHED WHITE FLOUR - APPROVAL AGENTS
2013-1900	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Scott Talbot Gavis Pharmaceuticals, LLC	GAVIS PHARMACEUTICALS, SOMERSET, NJ - EIR (03/05/2010)
2013-1901	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Sontag THE NEW YORK TIMES	SUBOXONE, SUBUTEX, BUTRANS - AERS (10/08/2002 - 03/10/2013)
2013-1902	03/12/2013 04/09/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Charles Hunger Charles Hunger	BOSTON SCIENTIFIC PROTEGEN MESH SLING - RECALL LETTER 1/22/99, CORR
2013-1903	03/12/2013 04/09/2013	FDA/OF/CFSAN/OCD/EOS/	Mike Snodgrass TriSep Corporation	EXEMPTION FILE 97-016 FOOD CONTACT
2013-1904	03/12/2013 04/09/2013	FDA/OF/CFSAN/OCD/EOS/	Andrew Sullivan WINSTON & STRAWN LLP	WESTERN SUGAR COOPERTAIVE, MICHIGAN SUGAR COMPANY, MICHIGAN SUGAR COMPANY ETC - CORR RE HIGH FRUCTOSE CORN SYRUP (01/01/2005 - 03/11/2013)
2013-1905	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kyle Davis MICHIGAN STATE UNIVERSITY	SSRI DRUGS - AERS
2013-1906	03/12/2013 04/09/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John D. Morris 4LIFE RESEARCH LC	CBS NUTRITION, LINDON, UT - EIR AUGUST 2012
2013-1907	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	gerald cagle cagle, gerald d	AMYVID - SBA

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2013-1908	03/12/2013 04/09/2013	FDA/OF/CFSAN/OCD/EOS/	Andrew Sullivan WINSTON & STRAWN LLP	CAPRI SUN MOUNTAIN COOLER - CORR RE SUGAR
2013-1909	03/12/2013 04/09/2013	FDA/OF/CFSAN/OCD/EOS/	Doe J	PHENYLKETONURIS, ASCOBIC ACID - CAERS
2013-1910	03/12/2013 04/09/2013	CVM/OCD/	JEFFREY S GULLEY GOVERNMENT ACCOUNTABILITY PROJECT	SALE OF ANTIMICROBIAL DRUGS FOR USE IN FOOD- PRODUCING ANIMALS - RECS
2013-1911	03/12/2013 04/09/2013	FDA/OGROP/OR/SE-FO/ATL- DO/ATL-CB/	CATHY L BURGESS ALSTON & BIRD LLP	HOSPIRA, ROCKY MOUNT, NC - 483, CORR 1/13 TO PRESENT
2013-1912	03/12/2013 04/17/2013	ORA/ ORA/ FDA/OGROP/OR/CE-FO/BLT- DO/BLT-CB/ FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/OR/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/OR/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/OR/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/OR/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/OR/SW-FO/KAN- DO/KAN-CB/ ORA/ORO/DFS/ ORA/ORO/DFS/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	TRICYCLAZOLE, BUPROFEZIN, ISOPROTHIOLANE IN RICE - METHODOLOGY VALIDATION TESTING
2013-1913	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH A BATTS ULMER & BERNE LLP	DR 180-II K001288, HOLTER FOR WINDOWS K930564, DR 180+OXY K004007 (CERTIFIED)
2013-1914	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	PETER HUMPHRIES DUNCAN BASHEER HANNON	DEPUY - LCS3PEG MOD ROT PATELLA POROCOAT, LCS INSET TROCHLEAR CMLPTS, MDRS
2013-1915	03/12/2013 04/09/2013	FDA/OGROP/OR/SE-FO/FLA- DO/FLA-CB/	JAMES J GIBSON JR PHD INTEGRITY LIFE SCIENCES	EXCITE MEDICAL CORP - 482S, 483S, CORR, ATTACHMENTS, ETC

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2013-1916	03/12/2013 04/09/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	K MICHELLE VASSALLO LINCARE INC	RAYTEL CARDIAC SERVICES INC (PHILIPS REMOTE CARDIAC SERVICES), CT - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-1917	03/12/2013 04/09/2013	OC/OOPD/	CORBIN, D JONATHAN	PRIMOCURE PHARMA INC - 3-BROMOPYRUVATE RECS
2013-1918	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	LORI SMITH MERIAL	THIODIPROPIONIC ACID, DILAURYL & DISTEARYL ESTERS - PHARMACOLOGY & TOXICOLOGY FINAL RPT
2013-1919	03/12/2013 04/09/2013	FDA/OMPT/CTP/OD/	REGINALD C BARRETT JR CAROLINA TOBACCO MANUFACTURERS LLC	ALTERNATIVE BRANDS INC - INGREDIENT LIST
2013-1920	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEAN IRWIN RA MEDICAL SYSTEMS INC.	SPECTRANETICS - CVX-300 EXCIMER SYS SERIVCE MANUAL
2013-1921	03/12/2013 04/09/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	SAFECOR HEALTH LLC, COLUMBUS, OH - EIRS, 483S, WARNING LTRS 2010-2012
2013-1922	03/12/2013 04/09/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	SAFECOR HEALTH LLC, WOBURN, MA - EIRS, 483S, WARNING LTRS 2010-2012
2013-1923	03/12/2013 04/09/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	UDL LABS, ROCKFORD, IL - EIRS, 483S, WARNING LTRS 2010-2012
2013-1924	03/12/2013 04/09/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KAREN DONOVAN MEDPHARMA PARTNERS LLC	CARDINAL HEALTH, ZANESVILLE, OH - EIRS, 483S, WARNING LTRS 2010-2012
2013-1925	03/12/2013 04/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nanette LoDolce Baker Botts	K924969
2013-1926	03/12/2013 04/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OM/DDM/	Heather Munro Prescott CENTRAL CONNECTICUT STATE UNIVERSITY	NDA 18680
2013-1927	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K993802
2013-1928	03/13/2013	FDA/OC/OES/DFOI/	Johnathan Rickman	FOIA REQUEST LOG (03/04/2013 - 03/08/2013)

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	04/10/2013		FDANEWS	
2013-1929	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Goldsmith CANACCORD GENUITY	REMODULIN - COMPLETE RESPONSE LETTER
2013-1930	03/13/2013 04/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Thomas McGrath AMRI-Burlington	DSM PHARMACEUTICALS, INC, GREENVILLE, NC - WARNING LETTER AND REPSONSES (04/02/2012 - 03/12/2013)
2013-1931	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachael Flanagan Leopold Law, PA	GLOBUS MEDICAL, INC TRANSITION 2 LEVEL IMPLANT - ADVERSE EVENTS, IMPLANT TRACKING STICKERS, LOT NUMBERS ETC (07/13/2012 - 03/12/2013)
2013-1932	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	7748236 7750172 7752230 ETC - MEDWATCH REPORTS
2013-1933	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	jesse polansky jmp	CRESTOR - SUBMISSION AND APPROVAL RECS
2013-1934	03/13/2013 04/10/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	William D. Sanders McGivney & Kluger, P.C.	NBTY - RECALL RECS
2013-1935	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Ross Ross, Kevin	AMBIEN - PEDIATRIC WRITTEN REQUEST
2013-1936	03/13/2013 05/06/2013	ORA/ ORA/	Carol Reynolds Reynolds, Carol A	NUTRO - COMPLAINTS (08/01/2012 - 03/11/2013)
2013-1937	03/13/2013 04/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Mary Gustafson PPTA	PLASMA DONOR FATALITIES - TABLE OF FINAL CONCLUSIONS FY12
2013-1938	03/13/2013 04/10/2013	FDA/OO/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO SECURITIES	KALYDECO - AERS

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2013-1939	03/13/2013 04/10/2013	CVM/OCD/	John Hallberg Hallberg, John W	NADA 134930 FOIA SUMMARY
2013-1940	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	3696536 3755232 4040349 ETC - MEDWATCH REPORTS
2013-1941	03/13/2013 04/10/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Doe J	COMPLAINT 130596, FOLLOW UP
2013-1942	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stryker Sustainability Solutions STRYKER SUSTAINABILITY SOLUTIONS	K121240, K032676, K122511
2013-1943	03/13/2013 04/10/2013	FDA/OMPT/CTP/OD/	Lauren Channell Siegfried & Jensen	ELECTRONIC CIGARETTES - ADVERSE EVENTS
2013-1944	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Stryker Sustainability Solutions STRYKER SUSTAINABILITY SOLUTIONS	K31011,K092879
2013-1945	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	PROMETRIUM - AERS
2013-1946	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Banwatt Gilbert's LLP	DEAR HEALTH CARE PROFESSIONAL LETTER RE DRUGS 2/3/89
2013-1947	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE KILLEN HILLYARD WAHLBERG ET AL	ADDERALL XR - APRVL
2013-1948	03/13/2013 04/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JACQUELINE KILLEN HILLYARD WAHLBERG ET AL	AMPHETAMINE; DEXTROAMPHETAMINE - APRVL

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2013-1949	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACQUELINE KILLEN HILLYARD WAHLBERG ET AL	ADDERALL - APRVL
2013-1950	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELISA TOSTADO STRYKER SUSTAINABILITY SOLUTIONS	REPROCESSED ENDOSCOPIC TROCARS K121240; ENDOPATH BLADELESS TROCAR K032676; ENDOPATH BLADELESS TROCAR K122511
2013-1951	03/13/2013 04/10/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	MATTHEW E. KONOSKY UBS GLOBAL ASSET MANAGEMENT	IMPAX LABS, HAYWARD, CA - 483
2013-1952	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN GREENHAM SYSTAGENIX	RADIOMETER COMBINED O2, CO2, SP02 K043003; PERIMED TRANSCUTANEOUS O2, CO2 MONITOR K990960
2013-1953	03/13/2013 04/10/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	ALEXIS ERAZO MEDCOMP INC	MEDCOMP, HARLEYSVILLE, PA - EIR 5/03
2013-1954	03/13/2013 04/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ELLIOT FAVUS, M.D. FAVUS INSTITUTIONAL RESEARCH LLC	BAXTER - GAMMA GARD LIQUID VAERS 1/06 TO PRESENT
2013-1955	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LIANE LaROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	LIFESCAN INC - ONE TOUCH VERIO BLOOD GLUCOSE MONITORING SYS INC K093745
2013-1956	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	BRUCE D. GOODMAN STEINBERG GOODMAN & KALISH	SYNTHES - PANGAEA SYS APRVL, MDRS, EIRS, ETC 2000 TO PRESENT
2013-1957	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID C. WEBER BEHREND & ERNSBERGER PC	PRENISON - LBLG CHANGES 1990 TO PRESENT
2013-1958	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZANNE KETTERIDGE NEW HAMPSHIRE PUBLIC DEFENDER	FETANYL - AERS 1997 TO 2013
2013-1959	03/13/2013 04/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	JEANNE BAKER DEPUY ORTHOPAEDICS INC	HIP REPLACEMENT CONTENT
2013-1960	03/13/2013 04/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REA TANOSHIMA, MD HOSPITAL FOR SICK CHILDREN	KEPPRA (LEVETIRACETAM) - ISRS 6549236, 3853599, 7155070, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-1961	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HUMIRA - SUPPLEMENTAL APPROVAL RECS
2013-1962	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Tewey Cerium Pharmaceuticals	CORTROSYN - SBA
2013-1963	03/14/2013 04/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Tina O'Brien Terumo BCT	BK090058
2013-1964	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Augusta Cerny Shire Regenerative Medicine	K061711
2013-1965	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Babos IPD ANALYTICS LLC	ANDA 078813, ANDA 078817, ANDA 090849 ETC - APPROVAL LETTERS
2013-1966	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ OM/DDM/	Kevin Wyckoff ORTHO CLINICAL DIAGNOSTICS INC	RECEPTAN-N - RECLASSIFICATION PETITION
2013-1967	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Amy Kincanon LEXISNEXIS COURTLINK INC	2012-7732
2013-1968	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arvinder Singh Kirax Corp.	HYDROCODONE, ACETAMINOPHEN, HYDROCODONE - NDA RECS
2013-1969	03/14/2013 04/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Michelle D. Johnson Johnson, Michelle D	INFLUENZA VACCINE - ADVERSE EVENTS IN MARYLAND (01/01/2009 - 01/01/2013)
2013-1970	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Dittman Vertex Pharmaceuticals Incorporated	BLA 125427

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2013-1971	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EXELON - PROMOTIONAL RECS
2013-1972	03/14/2013 04/11/2013	FDA/OO/OFBA/OAGS/	MICHAEL MORISY MUCKROCK NEWS	BOOZ ALLEN HAMILTON - CONTRACTS, FINAL RPTS LAST 5 YRS
2013-1973	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/	A LUKE SMITH FARUQI & FARUQI LLP	SANDOZ - SKELAXIN ANDA 40-445 EIRS, CORR, RECS
2013-1974	03/14/2013 04/11/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	RACK, RALPH	CYCLE-TEX INC, DALTON, GA - REMOVAL OF MEDICAL DVCS PHOTOS, CORR, RECS
2013-1975	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KELLER BRUNO INDEPENDENT LIVING AIDS INC	WHEELCHAIR ELEVATORS MARKETING IN THE US - TRADE COMPLNT 9/5/12
2013-1976	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELSPETH CALLAHAN INDEPENDENCE LEGAL SUPPORT	PALATIN TECHNOLOGIES - PT141 (BREMELANOTIDE) PHASE III CLNCL TRIAL APPL LTR 8/07
2013-1977	03/14/2013 04/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLCORD, JARED S	BAVITUXIMAB - APRVL OF BREAKTHROUGH DESIGNATION APPL
2013-1978	03/14/2013 04/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	HILL, MICHAEL	BIOVEST - BIOVAX ID MTG TRANS 11/2/12
2013-1979	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	EBI LLC - SOLITAIRE-C CERVICAL SPACER SYS K113796
2013-1980	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	SYNTHES SPINE CO LP - SYNTHES ZEO-P K112459
2013-1981	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KIM FINCH CHOICE SPINE LP	RSB SPINE LLC - INTERPLATE C K092070

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2013-1982	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	RSB LLC - INTERPLATE INTERBODY FUSION DVC K071922
2013-1983	03/14/2013 04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM FINCH CHOICE SPINE LP	STRYKER CORP - HOFFMANN 3 MODULAR EXTERNAL FIXATION SYS K121252
2013-1984	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-2061
2013-1985	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-1546
2013-1986	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-8205
2013-1987	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-2951
2013-1988	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5871
2013-1989	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-3578
2013-1990	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-7023
2013-1991	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-3778
2013-1992	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-3884
2013-1993	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-1039
2013-1994	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-6310
2013-1995	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-8374
2013-1996	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4231
2013-1997	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOI LOG 2/25/13-3/1/13
2013-1998	03/14/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND	CLOSED FOI LOG 2/18-22/13

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	04/11/2013		FDA REVIEW/FDA WEBVIEW	
2013-1999	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI LOG 2/18-22/13
2013-2000	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED FOI LOG 2/25/13-3/1/13
2013-2001	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 2/25/13-3/1/13
2013-2002	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	FOI LOG 2/18-22/13
2013-2003	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI LOG 2/25/13-3/1/13
2013-2004	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 2/18-22/13
2013-2005	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOI LOG 2/25/13-3/1/13
2013-2006	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/18/13-2/22/13
2013-2007	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 2/25/13-3/1/13
2013-2008	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 2/18-22/13
2013-2009	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 2/18-22/13
2013-2010	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 2/25/13-3/1/13
2013-2011	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/18-22/13
2013-2012	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/25/13-3/1/13
2013-2013	03/14/2013	FDA/OC/OES/DFOI/	DEBI COHEN	DAILY LOG 2/25/13-3/1/13

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	04/11/2013		WOLTERS KLUWER LAW & BUSINESS	
2013-2014	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 2/18-22/13
2013-2015	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/25/13-3/1/13
2013-2016	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/18-22/13
2013-2017	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 2/25/13-3/1/13
2013-2018	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 2/18-22/13
2013-2019	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 2/18-22/13
2013-2020	03/14/2013 04/11/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 2/25/13-3/1/13
2013-2021	03/15/2013 04/12/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMAS O HELTON BAKER DONELSON ET AL	MIR-CON LLC, CENTRAL CITY, PA - EIR, 483 6/7/12, CORR 6/19/12, ETC
2013-2022	03/15/2013 04/12/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	GORDON JOHNSTON GORDON JOHNSTON REGULATORY CONSULTANTS LLC	HOSPIRA, ROCKY MOUNT, NC - 483 1/1-31/13, 2/20/13-3/10/13
2013-2023	03/15/2013 04/12/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	K MICHELLE VASSALLO LINCARE INC	CARDIAC EVALUATION SERVICES INC, CT - ERIS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-2024	03/15/2013 04/12/2013	ORA/OE/ ORA/OE/	GREENBERG, BEATRICE	TOTAL NUMBER OF CLASS I AND CLASS II FOOD RECALLS FY2012
2013-2025	03/15/2013 04/12/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	HILL LABS, FRAZER, PA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2026	03/15/2013 04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	HTRD GROUP HONG KONG LTD, HONG KONG, CHINA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2027	03/15/2013 04/12/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	ADVANCED BACK TECHNOLOGIES INC, HAUPPAUGE, NY - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2028	03/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES J GIBSON JR	UNIVERSAL PAIN TECHNOLOGY CANADA INC, PRINCE GEORGE, CANADA - EIRS, 482S, 483S, ETC 1/09 TO

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	04/12/2013		INTEGRITY LIFE SCIENCES	PRESENT
2013-2029	03/15/2013 04/12/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	JAMES J GIBSON JR INTEGRITY LIFE SCIENCES	NORTH AMERICAN MEDICAL CORP, MARIETTA, GA - EIRS, 482S, 483S, ETC 1/09 TO PRESENT
2013-2030	03/15/2013 04/12/2013	FDA/OGROP/ORAPPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN K GRANT ROBBINS GELLER ET AL	IMPAX LABORATORIES INC - RYTARY (IPX066) CMLPTS, INVESTIGATIONS,RPTS, ETC 2010 TO 2013
2013-2031	03/15/2013 04/12/2013	FDA/OGROP/ORAPPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	JOHN K GRANT ROBBINS GELLER ET AL	IMPAX LABORATORIES INC - 483S, COMM, WARNING LTRS 2010- TO 2013
2013-2032	03/15/2013 04/12/2013	FDA/OF/CFSAN/OCDEOS/ FDA/OC/OES/	LAURA TURNER JUDICIAL WATCH	GLUTEN-FREE LBLG - CORR, CONTACTS WITH CELIAC DIEASE ALLIANCE, PAMELA'S PRODUCTS, OFFICE OF INFORMATION AND REGULATORY AFFAIRS (OIRA), ETC
2013-2033	03/15/2013 04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	JASON SMITH BEDFONT SCIENTIFIC LTD	TABATABA BREATH CO MONITOR K080278
2013-2034	03/15/2013 04/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KOBAYASHI, RIEKO	GUIDELINES FOR CLINICAL EVALUATION OF LIPID-ALTERING AGENTS IN ADULTS AND CHILDREN
2013-2035	03/15/2013 04/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) - AERS 5/12 TO PRESENT
2013-2036	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF223200850015I - CONTRACT, MODIFICATIONS, ORDERS
2013-2037	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF223200850021I - CONTRACT, MODIFICATIONS, ORDERS
2013-2038	03/15/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS	HHSF223200850019I - CONTRACT, MODIFICATIONS, ORDERS

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	04/12/2013		FOIA GROUP INC	
2013-2039	03/15/2013 04/12/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF223200850020I - CONTRACT, MODIFICATIONS, ORDERS
2013-2040	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5860
2013-2041	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4677
2013-2042	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5904
2013-2043	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5494
2013-2044	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5632
2013-2045	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5653
2013-2046	03/15/2013 04/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4156
2013-2047	03/15/2013 04/12/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	David Mangione Govzilla, Inc.	HOSPIRA, MCPHERSON, KS - EIR (10/01/2012 - 11/01/2012)
2013-2048	03/15/2013 04/12/2013	ORA/OCI/ ORA/OCI/ FDA/OGROP/ORAPPA-FO/LOS-DO/LOS-CB/	JOSEPH MASI SPORTS RESEARCH IN SAN PEDRO CALIFORNIA	SPORTS RESEARCH - INVESTIGATION
2013-2049	03/15/2013 04/12/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	David Mangione Govzilla, Inc.	CATALENT PHARMA SOLUTIONS LLC, MORRISVILLE, NC - EIR 02/14/13
2013-2050	03/15/2013 04/26/2013	FDA/OC/OES/DFOI/	David Mangione Govzilla, Inc.	483S RELEASED SINCE 04/13/2012
2013-2051	03/18/2013 04/15/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	HOSPIRA, ROCKY MOUNT, NC - EIR, 483, WARNING LETTER
2013-2052	03/18/2013 04/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Aegis Regulatory Inc. AEGIS REGULATORY INC	CAROL COLE COMPANY TRINITY WRINKLE REMOVER DEVICE - USER MANUAL, PREDICATE CHART, OUTER LABEL
2013-2053	03/18/2013 04/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Hilts Cenestra, LLC	RILUZOLE - SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2054	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Hirte Boston Scientific Endoscopy	K050578
2013-2055	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	NESINA (ALOGLIPTIN BENZOATE - AERS, ANALYSIS, DETAILED REPORTS, SAFETY/EPIDEMIOLOGY REPORTS
2013-2056	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	TRADJENTA (LINAGLIPTIN) - AERS, ANALYSIS, DETAILED REPORTS, ETC
2013-2057	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Fawcett Carroll Quality Consult, Inc.	NDA 022029
2013-2058	03/18/2013 04/15/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Christine Garner RECORDTRAK	NATIONAL MEDICAL SERVICES LABS, WILLOW GROVE, PA - 483, LAB RESULTS (01/03/2006 - 03/14/2013)
2013-2059	03/18/2013 04/15/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Jennifer Moore Regard Law Group	FEED SAMPLE 750441
2013-2060	03/18/2013 04/15/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Christine Garner RECORDTRAK	MEDTOX LABORATORIES, ST PAUL, MN - 483, EIR (01/03/2006 - 03/14/2013)
2013-2061	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Azanta A/S Azanta A/S	METRONIDAZOLE - SBA
2013-2062	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Augusta Cerny Shire Regenerative Medicine	K113104
2013-2063	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Wright Wright, Richard	STRYKER REJUVENATE, STRYKER ABG - INSTRUCTIONS FOR USE
2013-2064	03/18/2013 04/15/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Linda Bowen SANOFI	DOW CHEMICAL CO, PLAQUEMINE, LA - EIR (02/07/2013 - 02/13/2013)
2013-2065	03/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Augusta Cerny	K123356

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	04/15/2013		Shire Regenerative Medicine	
2013-2066	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melanie Johnson none	K103392
2013-2067	03/18/2013 04/15/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Peter Gallagher ZIFF BROTHERS INVESTMENTS	VALEANT PHARMACEUTICALS - AERS
2013-2068	03/18/2013 04/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Kristan Phillips MacroGenics	GENENTECH - 483 (03/01/2012 - 03/14/2013)
2013-2069	03/18/2013 04/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Melanie Johnson none	K013931
2013-2070	03/18/2013 04/15/2013	FDA/OF/CFSAN/OCDE/EOS/	Maria Jesus Perez Columbia University (student)	ENERGY DRINKS - AERS, COMPLAINTS
2013-2071	03/18/2013 06/07/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	TYLER KENYON NORTHCOAST RESEARCH	STRYKER CORP, PORTAGE, MI - WARNING LTR 11/12; INTEGRA LIFESCIENCES, PALINSBORO, NJ - WARNING LTR; INTEGRA LIFESCIENCES, PUERTO RICO - CO RESP
2013-2072	03/18/2013 04/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAL KAHAN LEV EL DIAGNOSTICS OF HEART DISEASES LTD	LEV EL LTD - HEARTTRENDS K021825; BIOSENSOR CORP - AMBULATORY (HOLTER) RECORDING SYS K950944
2013-2073	03/18/2013 04/15/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	MARGARET M. GROVES, JD. DUKE UNIV/SCHOOL OF MEDICINE	DR KENNETH W MAHAFFEY, DUKE CLNCL RESEARCH INSTITUTE, DURHAM, NC - EIR 8/20-24/12
2013-2074	03/18/2013 04/15/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	HAYGOOD, TRACY	INDIVIDUAL RECS
2013-2075	03/18/2013 04/15/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	HOLLAND, CHRIS	MARQIBO KIT (VINCRIStINE SULFATE) NDA 202497 APRVL
2013-2076	03/18/2013 04/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	MATTHEW E. KONOSKY UBS GLOBAL ASSET	IMPAX LABS, HAYWARD, CA - 483 7/09 TO 8/09

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			MANAGEMENT	
2013-2077	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PEGGY J. BERRY AMARIN PHARMA INC	VASCEPA (ICOSAPENT ETHYL) NDA 202-057 - UNREDACTED RVW
2013-2078	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN K. GRANT ROBBINS GELLER ET AL	IMPAX LABS INC - FENOFIBRATE ANDA 75-868 CMLNLS, INVESTIGATIONS 2010 TO 2013
2013-2079	03/18/2013 04/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN K. GRANT ROBBINS GELLER ET AL	IMPAX LABS INC - CONCERTA NDA 21-121 CMLNLS, INVESTIGATIONS 2010-2013
2013-2080	03/18/2013 04/15/2013	FDA/OF/CFSAN/OCD/EOS/	GERALDINE E. EDENS BAKER & HOSTETLER, LLP	ALBEMARLE CORP - FCN 1197
2013-2081	03/18/2013 04/15/2013	FDA/OF/CFSAN/OCD/EOS/	GERALDINE E. EDENS BAKER & HOSTETLER, LLP	ENVIRO TECH CHEMICAL SERVICES INC - FCN 944
2013-2082	03/18/2013 04/15/2013	FDA/OF/CFSAN/OCD/EOS/	GERALDINE E. EDENS BAKER & HOSTETLER, LLP	ENVIRO TECH CHEMICAL SERVICES INC - FCN 1098
2013-2083	03/18/2013 04/16/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	TRISH McGRADE PRITZKER OLSEN	SIMPLY THICK - INSP RECS, CORR
2013-2084	03/18/2013 07/19/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WILLIAM S. NORTON MOTLEY RICE LLC	HOSPIRA - INSP, INVESTIGATIONS 6/08 TO 1/12

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2013-2085	03/18/2013 04/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	JONES, GERALDINE	SANOFI-AVENTIS GROUP - FLUZONE VAERS
2013-2086	03/19/2013 04/16/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Law Offices of Ronald A. Marron Law Offices of Ronald A. Marron	NATURAL BALANCE, NATURE'S BALANCE, DIAL CORPORATION, ETC - COMM, CORR WITH FDA (01/01/2004 - 03/14/2013)
2013-2087	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Ryan Thompson Watts Guerra Craft LLP	A 3 MONTHS PANCREATIC STUDY IN A DIABETIC RODENT TREATED WITH SITAGLIPTIN - RESULTS, CONCLUSIONS
2013-2088	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Ryan Thompson Watts Guerra Craft LLP	A PROSPECTIVE OBSERVATIONAL COHORT STUDY TO EXAMINE THE INCIDENCE OF PANCREATIC MALIGNANCY AND THYROID NEOPLASM IN PATIENTS WITH TYPE 2 DIABETES MELLITUS INITIATED ON BYETTA COMPARED TO PATIENTS INITIATED OTHER ANTIDIABETIC AGENTS
2013-2089	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Ryan Thompson Watts Guerra Craft LLP	JANUMET, JANUMET XR - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2090	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Ryan Thompson Watts Guerra Craft LLP	ONGLYZA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2091	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Ryan Thompson Watts Guerra Craft LLP	BYDUREON - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2092	03/19/2013	FDA/OMPT/CDER/ORDIDP/	Ryan Thompson	JUVISYNC - OSE REVIEWS OR REPORTS RE AERS,

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	04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Watts Guerra Craft LLP	ANALYSIS OF AERS, DETAILED AERS ETC
2013-2093	03/19/2013 04/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John Shoemaker Visium	ALERE, SAN DIEGO, CA - 483, RESPONSE (01/01/2012 - 03/14/2013)
2013-2094	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	JANUVIA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2095	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	BYETTA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2096	03/19/2013 04/16/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	LORI MISCOE LORI MISCOE	COMPLAINT
2013-2097	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	VICTOZA - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2098	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	OSENI - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2099	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert W Caverly Indirect Cost	COMPASSIONATE INVESTIGATIONAL DRUG APPLICATION FOR CANNIBIS USE THROUGH THE 1968 DRUG SUPPLY PROGRAM
2013-2100	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ni Sun Alkermes, Inc.	ABILIFY MAINTENA - SBA
2013-2101	03/19/2013	FDA/OMPT/CDER/GRP/DIDP/	Sheila Albeke	NESINA, KAZANO, OSENI - APPROVAL PACKAGE

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	04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Oregon Health Science Center	
2013-2102	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kathy McGown FOXKISER	ELECTRONIC VERSION OF THE 32ND ANNUAL EDITION OF THE ORANGE BOOK
2013-2103	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Heather Goldman Goldman, Heather	HUMIRA - AERS
2013-2104	03/19/2013 05/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK090058
2013-2105	03/19/2013 04/16/2013	FDA/OF/CFSAN/OCD/EOS/	Jack Beidleman Idahoan Foods, LLC	CAERS162495
2013-2106	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K033181
2013-2107	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090871
2013-2108	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	ESSURE - CLASSIFICATION AS CLASS III DEVICE, PREMARKET APPROVAL
2013-2109	03/19/2013 04/16/2013	FDA/OF/CFSAN/OCD/EOS/	Sage Leehey University of Nevada, Reno	FDA'S DECISION TO RECOGNIZE GENETICALLY MODIFIED FOOD ORGANISM AS GENERALLY RECOGNIZED AS SAFE
2013-2110	03/19/2013 04/16/2013	FDA/OC/OES/DFOI/	Andrew Finkelstein Susquehanna Financial Group	HOSPIRA, ROCKY MOUNT, NC - 483 MARCH 2013
2013-2111	03/19/2013 04/16/2013	FDA/OGROP/ORR/SE-FO/FLA-DO/FLA-CB/	Scott Fawcett Carroll Quality Consult, Inc.	KAPPA LABORATORIES, MIAMI, FL - 483, EIR 2003 TO 2013
2013-2112	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	CELESTONE 6MG INJECTABLE STEROID - AERS
2013-2113	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Rehorst Dentaurum, Inc.	K942667

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2013-2114	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	ALOGLIPTIN - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2115	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	JENTADUETO - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2116	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	KOMBIGLYZE XR - OSE REVIEWS OR REPORTS RE AERS, ANALYSIS OF AERS, DETAILED AERS ETC
2013-2117	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ryan Thompson Watts Guerra Craft LLP	PANCREATIC CANCER, PANCREATITIS - SAFETY OR EPIDEMIOLOGICAL STUDIES, SAFETY CONCERNS, AND INCRETIN MIMETIC CLASS OF DRUGS
2013-2118	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elisa Hebb Elisa Hebb	K112119 SAFETY AND EFFECTIVENESS SUMMARY
2013-2119	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K983016
2013-2120	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 77991
2013-2121	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K050906
2013-2122	03/19/2013 04/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL, SYLMAR, CA - EIR EXHIBITS 1-42, CMLPTS, INVESTIGATIONS, ETC
2013-2123	03/19/2013 04/16/2013	FDA/OF/CFSAN/OCD/EOS/	KEVIN W LEONARD GRUNFELD DESIDERIO ET AL	SEIKO MARINE SDN BHD, MALAYSIA - INTERNATIONAL INSPS 1993 TO PRESENT
2013-2124	03/19/2013 04/16/2013	ORA/ ORA/	DANIEL R LAPINSKI ESQ WILENTZ GOLDMAN & SPITZER PA	RAM MEDICAL INC - COUNTERFEIT POLYPROPYLENE SURGICAL MESH RECS

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		ORA/OCI/ ORA/OCI/		
2013-2125	03/19/2013 04/16/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	DONALD N BLUE ZETETIC INC	CTNS SIM SENS IOSMIL SOY TSCW10592719 - RECS
2013-2126	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	NATALIE N SANDERS LATHAM & WATKINS LLP	ISONEA (KARMELSONIX) - PULMOTRACK 2020 SYS K102229
2013-2127	03/19/2013 04/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2013-2128	03/19/2013 04/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	CHARLES CELESTE EAS CONSULTING GROUP LLC	HERBS OF LIGHT, ALACHUA, FL - 483S 8/1/12-10/1/12
2013-2129	03/19/2013 04/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS T67081, KEITH	MARINOL. CANNABINOIDS - SBA, ADDRESS OF MFRS, CLNCL RECS, ETC
2013-2130	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHLOE BOWER SYNGEN INC	MEDTRONIC SOFAMOR DANEK USA INC - MAGELLAN AUTOLOGOUS PLATELET SEPARATOR SYS BK040068
2013-2131	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MDR 2963226
2013-2132	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID BLOCH MEDTRONIC	CARDIOMEMS - WARNING LTR RESP
2013-2133	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY G STANIFORD NIPRO Diagnostics	MW5029053
2013-2134	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	SILVERSTEAM AND DERMASEPT K093227
2013-2135	03/19/2013 04/16/2013	ORA/ ORA/	NORAH BURTON FOODMATCH INC	ENTRY #DP4-0615057-4 - LAB ANALYSIS
2013-2136	03/19/2013 04/16/2013	ORA/ ORA/	NORAH BURTON FOODMATCH INC	GREEN CASTEL VETRANO OLIVES ENTRY #NE9-9502212-0/10-1 - LAB ANALYSIS
2013-2137	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN L ROWE STRYKER INCUBATION OF MEDICAL TECHNOLOGY	BLUE BELL TECHNOLOGIES INC - NAVIOPFS K121936
2013-2138	03/19/2013 04/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBIN L ROWE STRYKER INCUBATION OF	STANMORE IMPLANTS WORLDWIDE LTD - SCULPTOR ROBOTIC GUIDANCE ARM K121765

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			MEDICAL TECHNOLOGY	
2013-2139	03/19/2013 04/16/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	PATRICIA L REGENYE Celgene Corporation	HERBERT BARAF, ARTHRITIS RHEUMATISM ASSOC, WHEATON, MD - 483S 3/07 TO PRESENT
2013-2140	03/19/2013 04/16/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	MARTIN MOLLEN, ARIZONA RES CTR, PHOENIX, AZ - 483S 3/02 TO PRESENT
2013-2141	03/19/2013 04/16/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	PATRICIA L REGENYE Celgene Corporation	BARRY WINSTON, NORTH HOUSTON GASTROENTEROLOGY CLIN, HOUSTON, TX - 483S 4/05 TO PRESENT
2013-2142	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	DANA TEGZOVA, RHEUMA INST, PRAGUE, CZE - 483S 10/10 TO PRESENT
2013-2143	03/19/2013 04/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L REGENYE Celgene Corporation	REMO PANACCIONE, PETER LOUGHEED CTR, CALGARY, CANADA - 483S 1/07 TO PRESENT
2013-2144	03/19/2013 04/16/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	PATRICIA L REGENYE Celgene Corporation	DALE BRAMLET, FLORIDA ORTHO ASSOC, ST PETERSBURG, FL - 483S 6/06 TO PRESENT
2013-2145	03/20/2013 04/17/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Sabrina Korber CNBC Business News	INTUITIVE SURGICAL - CORR WITH FDA (01/01/1997 - 03/19/2013)
2013-2146	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Neos Surgery S.L. Neos Surgery S.L.	K091432
2013-2147	03/20/2013 04/17/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	HERBALIFE INTERNATIONAL, LOS ANGELES, CA - EIR ATTACHMENTS 05/18/07-05/22/2007
2013-2148	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	HERBALIFE, SUZHOU, CHINA - EIR, 483
2013-2149	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ginger Neil Ripple, LLC	K071364
2013-2150	03/20/2013 04/17/2013	ORA/ ORA/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	JoNel Aleccia MSNBC.COM	MED PREP CONSULTING INC, TINTON FALLS, NJ - 483 (03/19/2001 - 03/19/2013)
2013-2151	03/20/2013	ORA/	Prashanth Jayaram	ST JUDE MEDICAL - FIRST UPDATE TO 01/01/2013 WARNING LETTER

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	04/17/2013	ORA/	CIG	
2013-2152	03/20/2013 04/17/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S 02/21/2013 TO 03/19/2103
2013-2153	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Rachel Johnson FOI Services, Inc.	KAN PAK, ARKANSAS CITY, KAN - 483, EIR TWO MOST RECENT
2013-2154	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Bio-Matrix Scientific Group, Inc. / Regen BioPharma, Inc Schayltz, Seth	BIO-MATRIX SCIENTIFIC GROUP, INC, HEMAXELLERATE, REGEN BIOPHARMA - IND RECS
2013-2155	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ana Cabrera KMGH-TV	HGH - AERS; REQUESTS TO USE DRUG OFF-LABEL (1/01/2008 - 03/19/2013)
2013-2156	03/20/2013 04/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Lori Hays Merz Aesthetics, Inc.	MERZ AESTHETICS, FRANKSVILLE, WI - EIR (3/14/2011 - 04/08/2011)
2013-2157	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Courtney Goldsworthy Witt & Goldsworthy, PLLC	COVIDIEN PERMACOL - UNTITLED LETTERS, WARNING LETTERS, RECALLS ETC
2013-2158	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ivan King Qi Oncology LLC	NDA 018154
2013-2159	03/20/2013 05/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Wendy Samford ThermoGenesis Corp.	BK940022
2013-2160	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (03/11/2013 - 03/15/2013)
2013-2161	03/20/2013 05/03/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	APPOINTMENT OF MITCH ZELLER AS CTP DIRECTOR

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-2162	03/20/2013 04/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	Pam Hayden NORTH AMERICAN SPINE SOCIETY	POWERPOINT PRESENTATIONS AT NASS SPINE FORUM
2013-2163	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K021939
2013-2164	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K023872
2013-2165	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	michael gibson gibson, michael	HOSPIRA, ROCKY MOUNT, NC - 483 (02/01/2013 - 03/19/2013)
2013-2166	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/	Doe J	MAXGXL - RECS RE BAN ON PRODUCT
2013-2167	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K021938
2013-2168	03/20/2013 04/17/2013	FDA/OGROP/ORAP/PA-FO/LOS- DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	INAMED, SANTA BARBARA, CA - EIR, 483
2013-2169	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	E.J. Smith Smith Associates	K060109
2013-2170	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith E.J. Smith	K040916
2013-2171	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K031748
2013-2172	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 77170
2013-2173	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 90922
2013-2174	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K992289
2013-2175	03/20/2013	FDA/OC/OES/DFOI/	Sonya Cressman	HISTORICAL PRODUCT LABEL, MEDICAL REVIEW, STATISTICAL REVIEW FOR 11 NDA/ BLA FILES

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	04/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	The British Columbia Cancer Agency	
2013-2176	03/20/2013 04/17/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	Lauren Hubbard CTI	DR STEPHAN GRUPP, CHILDREN'S HOSPITAL OF PHILADELPHIA - 483 (3/21/2005-3/24/2005)
2013-2177	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GHORMLEY 138287, ANTHONY	DEPAKOTE - AER
2013-2178	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/	ROBERT S. McQUATE, Ph.D. GRAS ASSOCIATES LLC	FCN 880
2013-2179	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIM C. CAPONE PORZIO LIFE SCIENCES	WYETH - SERAX LTR 4/23/75
2013-2180	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	CARL ZEISS MEDITEC AG - FORUM, FORUM ARCHIVE, FORUM VIEWER K122938; TOPCON CORP- IMAGENET PROFESSIONAL PC SOFTWARE SYS K082364; TOPCON MEDICAL SYS INC - SYNERGY K093313
2013-2181	03/20/2013 04/17/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICAL CORP	NOVARTIS PHARMACEUTICALS, EAST HANOVER, NJ - 483, CORR
2013-2182	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT .	XANTHAN GUM - AER 1969 TO 2013
2013-2183	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	JOHN MORRIS 4LIFE RESEARCH LC	USANA HEALTH SCIENCES, SALT LAKE CITY, UT - EIR
2013-2184	03/20/2013 04/17/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	JOHN MORRIS 4LIFE RESEARCH LC	NEWAYS INTERNATIONAL, SPRINGVILLE, UT - EIR (01/01/2012 - 03/19/2013)

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2013-2185	03/20/2013 04/17/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4Life	NATURE'S SUNSHINE PRODUCTS, PROVO, UT - EIR (01/01/2012 - 03/19/2013)
2013-2186	03/20/2013 04/17/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	WASATCH PRODUCT DEVELOPMENT LLC, DRAPER, UT - EIR (01/02/2012 - 03/19/2013)
2013-2187	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER, Esq WILSON SONSINI ET AL	ANDA D77302
2013-2188	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER, Esq. WILSON SONSINI ET AL	180 DAY MARGETING EXCLUSIVITY - MTG MINUTES, CORR
2013-2189	03/20/2013 04/17/2013	FDA/OGROP/ORAPASW-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	NELLSON NUTRACEUTICAL, SALT LAKE CITY, UT; NELLSON NUTRACEUTICAL, IRWINDALE, CA - EIR (01/01/2012 - 03/19/2013)
2013-2190	03/20/2013 04/17/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4Life	ALVITA HERBAL TEAS, AMERICAN FORK, UT - EIR (01/03/2012 - 03/19/2013)
2013-2191	03/20/2013 04/17/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	Mike Conley The McDowell News	BAXTER HEALTHCARE, NORTH COVE, NC - INSPECTION RECS 01/20/2012 - 03/20/2013
2013-2192	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ROQUETTE FRERES SA, LESTREM, FRANCE - EIR 2008
2013-2193	03/20/2013 04/17/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4Life	UNICITY NETWORK, EAST OREM, UT - EIR (01/02/2012 - 03/19/2013)
2013-2194	03/20/2013 04/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER, Esq. WILSON SONSINI ET AL	ANDA 77858
2013-2195	03/20/2013 04/17/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	John Morris 4Life	NUTRA FORCE, INC PARK CITY, UT - EIR (01/01/2012 - 03/19/2013)
2013-2196	03/20/2013	ORA/		COMPLAINT RECS

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	04/17/2013	ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Doe J	
2013-2197	03/20/2013 04/17/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Dennis Graves Avanti Polar Lipids, Inc.	AVANTI POLAR LIPIDS, INC, ALABASTER, AL - PREAPPROVAL INSPECTION (11/01/2012 - 01/31/2013)
2013-2198	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALYSON OLIVER OLIVER LAW GROUP	PHARMACEUTICAL INNOVATIONS INC - SONIC ULTRASOUND TRANSMISSION GEL CORR, Cmplnts
2013-2199	03/20/2013 04/17/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	TOBACCO MANUFACTURERS - EIR, 483 (08/08/2012- 03/18/2013)
2013-2200	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/	AMI V. GADHIA CONSUMERS UNION	INORGANIC & ORGANIC ARSENIC CONCENTRATIONS IN RICE & RICE PRODUCTS - TEST RESULTS
2013-2201	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	PEARD, BILLY	PINNACLE FOODS GROUP LLC - LOG CABIN SYRUP & BIRDS EYE FROZEN CORN CORR 2003 TO PRESENT
2013-2202	03/20/2013 04/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	PEYTON R. BIDDLE, III OSTERHOUDT PRILLAMAN ET AL	K031106
2013-2203	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	MARTINA BERNSTEIN PETA FOUNDATION	BOVINE SPONGIFORM ENCEPHALOPATHY - RPTS, STUDIES 1/08 TO PRESENT
2013-2204	03/20/2013 04/17/2013	FDA/OC/OES/DFOI/	DAVID GRYCZ SEDGWICK LLP	INFANT FORMULA RECS
2013-2205	03/20/2013 04/17/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDANEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC, CLNCL TRIAL FACILITIES - 483S 2/1-28/13

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2013-2206	03/20/2013 04/17/2013	FDA/OF/CFSAN/OCD/EOS/	SANDRA PIERCE BARON & BUDD PC	RESP TO LTR FROM WASHINGTON DEPT OF AGRICULTURE RE REPORTED FINDINGS OF LOW LEVELS OF LEAD IN SOME FOOD PRODUCTS COMMONLY CONSUMED BY CHILDREN
2013-2207	03/21/2013 04/18/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	NUTRACEUTICAL INTERNATIONAL, PARK CITY, UTAH - EIR (01/01/2012 - 03/19/2013)
2013-2208	03/21/2013 04/18/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	HTL STREFA, MARIETTA, GA - INSPECTION RESULTS (01/15/2013 - 03/01/2013)
2013-2209	03/21/2013 04/18/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	JOhn Morris 4Life	LIVING ESSENTIAL OILS, LEHI, UT - EIR (01/02/2012 - 03/19/2013)
2013-2210	03/21/2013 04/18/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ROQUETTE FRERES SA, LESTREM, FRANCE - EIR 2012
2013-2211	03/21/2013 04/18/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Beatrix Taylor Omeros Corporation	SOLIRIS - ORPHAN DRUG DESIGNATION APPLICATION, OOPD REVIEW OF REQUEST FOR ORPHAN DRUG DESIGNATION
2013-2212	03/21/2013 04/18/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	NOVARTIS CONSUMER HEALTH, INC, LINCOLN, NE - 483 (01/21/2013 - 02/22/2013)
2013-2213	03/21/2013 04/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beatrix Taylor Omeros Corporation	BLA 125166 - REVIEW SUMMARY
2013-2214	03/21/2013 04/18/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	TWIN LABS, AMERICAN FORK, UT - EIR (01/01/2012 - 03/19/2013) ;
2013-2215	03/21/2013 04/18/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	SCHIFF NUTRITION INTERNATIONAL, SALT LAKE CITY, UT - EIR (01/2012 - 03/19/2013)
2013-2216	03/21/2013 04/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER & HAMPTON, LLP	CELESTONE SOLUSPAN (BETAMETHASONE ACETATE/BETAMETHASONE SODIUM PHOSPHATE INJ) NDA 14-602/S056 - RECS
2013-2217	03/21/2013 04/18/2013	FDA/OF/CFSAN/OCD/EOS/	BACKMAN, ARI I	SA CONFISERIE LEONIDAS, ANDERLECHT, BELGIUM 8/16/12; BRUXELLES, BELGIUM 8/14/12 - EIRS
2013-2218	03/21/2013	FDA/OGROP/ORA/NE-FO/NYK-	JOHN WALSH	POLYMER CONVERSIONS INC, ORCHARD PARK, NY - EIRS,

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	04/18/2013	DO/NYK-DCB/	JAMES ALEXANDER CORP	483S, RECALLS 1/11 TO PRESENT
2013-2219	03/21/2013 04/18/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	JOHN WALSH JAMES ALEXANDER CORP	FILTRONA FIBERTEC, COLONIAL HEIGHTS, VA - EIRS, 483S, RECALLS 4/11 TO PRESENT
2013-2220	03/21/2013 04/18/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JOHN WALSH JAMES ALEXANDER CORP	CHEM-IMPEX INTERNATIONAL, WOOD DALE, IL - EIRS, 483S, RECALLS 4/09 TO PRESENT
2013-2221	03/21/2013 04/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT STEELE STRYKER MEDICAL	LINET SPOL SRO, SLANY, CZECH REPUBLIC - 483 10/29/12-11/1/12
2013-2222	03/21/2013 04/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK SCHOOF PROPUBICA	CETERO, HOUSTON, TX - RESEARCH VIOLATIONS RECS
2013-2223	03/21/2013 04/18/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	DAVID SALERNO, CHATTANOOGA HEART INST 1/28/92; RONALD MILLER, UNIV OF CALIFORNIA SAN FRANCISCO, SAN FRANCISCO, CA; VIRENDA DESAI, PHYSICIAN ALLIANCE RESEARCH CENTER, LONG BEACH, CA 3/17/08, ETC - 483S
2013-2224	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Beique Joanne Beique	K113544
2013-2225	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202971

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2013-2226	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Beique Joanne Beique	K072123
2013-2227	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Melissa Luras Watson Laboratories, Inc.	SKYLA NDA 203159 - CHEMISTRY REVIEW; MICROBIOLOGY REVIEW; SUMMARY REVIEW ETC
2013-2228	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn Kimberlee Washburn	K050438
2013-2229	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EVISTA - AERS
2013-2230	03/22/2013 04/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Martin N. Preiser GOLDBERG & GOLDBERG	METHADONE 10 MG - PACKAGE INSERTS
2013-2231	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Richard Bilton BBC News	BURZYNSKI CLINIC, BURZYNSKI RESEARCH INSTITUTE - 483(01/01/1995 - 03/21/2013)
2013-2232	03/22/2013 04/19/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Defense Nutrition Salmas Law Group	WISDOM PROTEINS INC, SAN DIEGO, CA - LABEL, PHOTOS
2013-2233	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	4Life 4LIFE RESEARCH LC	EXCEL INTERNATIONAL, INC, SANDY, UT - EIR
2013-2234	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	John Morris 4Life	XANGO, LLC, LEHI, UT - EIR (01/02/2012 - 03/20/2013)
2013-2235	03/22/2013 04/19/2013	FDA/OF/CFSAN/OCD/EOS/	Adrian Giraldo Soto Ecoflora SAS	CAP 2CO293
2013-2236	03/22/2013 04/19/2013	FDA/OF/CFSAN/OCD/EOS/	Elena De Marco Mataluni SpA	FAP 9A4779
2013-2237	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	Heather Greenslate BALYASNY ASSET MANAGEMENT	FDA FOIA LOG (01/01/2011 - 03/21/2013)
2013-2238	03/22/2013	FDA/OMPT/CDER/ORP/DIDP/	Terrence J. Donahue, Jr.	METOCLOPRAMIDE - MEDICAL REVIEWS

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	04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	McGlynn Glisson & Mouton	
2013-2239	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Doe J	INDIVIDUAL RECS
2013-2240	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Clint Matthews UNIVERSITY OF MISSOURI	K101793
2013-2241	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Patti Waller Marler Clark Law Firm	FDA SAMPLE #708461 LABORATORY TESTING RESULTS
2013-2242	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-2243	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	Heather Greenslate BALYASNY ASSET MANAGEMENT	FOIA LOGS (08/02/2007 - 12/31/2010)
2013-2244	03/22/2013 04/19/2013	OM/DDM/ OC/OM/OMP/DDM/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	JAZZ PHARMACEUTICALS - CITIZENS PETITIONS, REPSONSES
2013-2245	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ELSEVIER, ELSEVIER SCIENCE, REED TECHNOLOGIES - FOIA INVOICECS 01/01/2007 TO 12/21/2011
2013-2246	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanne Beique Joanne Beique	K110518
2013-2247	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	JAKAFI - AERS
2013-2248	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	John Morris 4Life	AGEL, LEHI, UT - EIR (01/02/2012 - 03/20/2013)
2013-2249	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	NU SKIN ENTERPRISES, PROVO, UT - EIR (01/02/2012 - 03/20/2013)
2013-2250	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERYN M. PEDDICORD PEDDICORD AND TOWNSEND	MISOPROSTOL (CYTOTEC) LBLG

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LLC	
2013-2251	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY M. WOLFE, MD PUBLIC CITIZEN HEALTH RESEARCH GROUP	SITAGLIPTIN - OES RVW 6/09
2013-2252	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leon Lambry Surgical Information Systems	K930492
2013-2253	03/22/2013 04/19/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	PATRICIA L. REGENYE Celgene Corporation	THOMAS ERVIN, FLORIDA CANCER SPECIALISTS, FT MYERS, FL - EIR, 483, CO RESP 4/12 TO PRESENT
2013-2254	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Lynn Cox Sinclair Research Center LLC	SINCLAIR RESEARCH CENTER, AUXVASSE, MO - EIR (06/09/2008 - 03/20/2013)
2013-2255	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn Kimberlee Washburn	K003111
2013-2256	03/22/2013 04/19/2013	FDA/OF/CFSAN/OCD/EOS/	Barbara Blakistone National Fisheries Institute	SURVEILLANCE SAMPLING OF MAHI MAHI FROM TAIWAN FOR PAST THREE YEARS
2013-2257	03/22/2013 04/19/2013	FDA/OO/OFBA/OAGS/	CHRISTOPHER E. POWELL MARATHON	09-223-SOL-0052
2013-2258	03/22/2013 04/19/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	John Morris 4Life	ASEPTIC SOLUTIONIS, CORONA, CA - EIR (01/02/2012 - 03/20/2013)
2013-2259	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	BASIC RESEARCH, SALT LAKE CITY, UT - EIR (1/02/2012 - 03/20/2013)
2013-2260	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sofia Bruera Blizzard & Nabers, LLP	TYSABRI - AERS
2013-2261	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S-040/ 21246 S-027 (TAMIFLU)
2013-2262	03/22/2013 04/19/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	John Morris 4LIFE RESEARCH LC	DESERET LABORATORIES, ST GEORGE, UT - EIR (01/02/2012 - 03/20/2013)
2013-2263	03/22/2013	ORA/	DONALD N. BLUE	ENTRY NO D01-0842601-2 - MARS CHOCOLATES

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	04/19/2013	ORA/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	ZETETIC	
2013-2264	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S048, 049/ 21246 S034, S035 (TAMIFLU)
2013-2265	03/22/2013 04/19/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	ENTRY NO D01-0842682-2 - MARS CHOCOLATES
2013-2266	03/22/2013 04/19/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	D01-0842143-5 - MARS CHOCOLATES
2013-2267	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S056/ 21246 S039 (TAMIFLU)
2013-2268	03/22/2013 04/19/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	DONALD N. BLUE ZETETIC	ENTRY NO D01-0842622-8 - UNCLE BENS RICE
2013-2269	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 21087 S062/ 21246 S045 (TAMIFLU)
2013-2270	03/22/2013 04/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Marc C. Sanchez Contract In-House Counsel and Consultant	K060846
2013-2271	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHISTINE P. BUMP GOODWIN PROCTER LLP	OTSUKA PHARMCEUTICAL CO LTD - ABILIFY MAINTENA KIT NDA 202-971 APRVL, LBLG, MED RVWS

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2013-2272	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHRYN L. BIBERSTEIN ALKERMES INC	OTSUKA PHARM CO - ABILIFY MAINTENA KIT APRVL, LBLG, MEDICAL RVW
2013-2273	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SOFIA BRUERA Blizzard & Nabers, LLP	TYSABRI (NATALIZUMAB) AER 1/05 TO 1/1/13
2013-2274	03/22/2013 04/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS, PHARM D	ACTAMINOPHEN & CODEINE PHOSPHATE ORAL SOLUTION; POTASSIUM CHLORIDE ORAL SOLUTION RED; ANTISPASMODIC ELIXIR, ETC - EVALUATION
2013-2275	03/22/2013 04/19/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	COLLEEN K. DUCAS SANOFI PASTEUR	MERIEUX SERUMS ET VACCINS - DCT C-3301
2013-2276	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	JOHNATHAN RICKMAN FDANEWS	ST JUDE MEDICAL PUERTO RICO LLC, ARECIBO, PR - 483 10/12
2013-2277	03/22/2013 04/19/2013	FDA/OC/OES/DFOI/	AMY DELINE SIDLEY AUSTIN LLP	ST JUDE MEDICAL - ALL REQUESTS RELATED TO 522 SURVEILLANCE
2013-2278	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-969 REQUEST LETTER
2013-2279	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1022 REQUEST LETTER
2013-2280	03/25/2013 04/22/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1415 REQUEST LETTER ONLY
2013-2281	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K022718
2013-2282	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alan Rorke Dr Alan Rorke	K053228
2013-2283	03/25/2013 04/22/2013	OC/OOPD/ FDA/OMPT/OSMP/OOPD/	Herriot Tabuteau Axsome Therapeutics Inc.	RALOXIFENE (EVISTA) - ORPHAN DESIGNATION REVIEW
2013-2284	03/25/2013 04/22/2013	OC/OL/	Jonathan J. Darrow Harvard Law Schol	REPORT TO CONGRESS REQUIRED BY SECTION 904 OF THE FDAAA
2013-2285	03/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K100349

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	04/22/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	
2013-2286	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K091733
2013-2287	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102860
2013-2288	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Luigi Xerri VenatoRx Pharmaceuticals, Inc.	MEROPENEM - IND RECS
2013-2289	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Debanjana Bhattacharya UNIVERSITY OF SOUTH DAKOTA	DEPLIN - APPROVAL PACKAGE
2013-2290	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100221
2013-2291	03/25/2013 04/22/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Myrna Booth Blank Park Zoo	SAMPLE 761686
2013-2292	03/25/2013 04/22/2013	FDA/OF/CFSAN/OCD/EOS/	Kris Callaert Techniplast Projects	FCN 631
2013-2293	03/25/2013 04/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH I. MARCHESE Bursor & Fisher, P.A.	ST JUDE MEDICAL - RECS RE PREMATURE EROSION IN RIATA AND RIATA ST (01/01/2005 - 03/22/2013)
2013-2294	03/25/2013 04/22/2013	ORA/OCI/ ORA/OCI/	Ken Cummings NA	WHITEHALL SPECIALTIES, WHITEHALL, WI, LACROSSE, WI, DMV USA - INVESTIGATION RECS
2013-2295	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2013-2296	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Woodling OXiGENE, Inc.	DR REDDY'S LABORATORY, INDIA - 483 01/01/07 TO 06/01/10

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2297	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kacie Carroll RN Barr & Mudford LLP	BODY BUILDING PRODUCTS AND HIDDEN STEROIDS: ENFORCEMENT BARRIERS - REPORT FROM MICHAEL LEVY ESQ TO SENATE SUBCOMMITTEE 2009
2013-2298	03/25/2013 04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Zhu Asia Dynamics Inc.	K952414
2013-2299	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	XTANDI - AERS
2013-2300	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	ICLUSIG - AERS
2013-2301	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Silverstein SIGMA CAPITAL MANAGEMENT LLC	KYPROLIS - AERS
2013-2302	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXO SMITH KLINE, WORTHING, UK - QAP
2013-2303	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	FABBRICA ITALIANA SINTETICI, MONTECCHIO, MAGGIORE, ITALY - EIR, 483, CO RESP 3/12
2013-2304	03/25/2013 04/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NEDD, CUTHBERT	CHEMOTHERAPY DRUGS - APRVD LIST
2013-2305	03/25/2013	FDA/OC/OES/DFOI/	DONALD E. SEGAL	CRYO LIFE, KENNESAW, GA - EIR, 483, WARNING LTR

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	04/22/2013		ALSTON & BIRD LLP	
2013-2306	03/25/2013 04/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA KINCANNON, Esq. KEEFE BARTELS CLARK ATTY AT LAW	STRYKER ORTHOPAEDICS 0 REJUVENATE MODULAR NECK STEMS K092561
2013-2307	03/25/2013 04/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA KINCANNON, Esq. KEEFE BARTELS CLARK ATTY AT LAW	STRYKER ORTHOPAEDICS - ABG II MODULAR NECK STEMS K092406
2013-2308	03/25/2013 04/22/2013	OM/DDM/	LAURA S. TUTTELL PHILLIPS LYTLE ET AL	DCT 75N-0062
2013-2309	03/25/2013 04/22/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON BURLING LLP	SE RVW PROCESS
2013-2310	03/25/2013 04/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WHITE W101640, JONATHAN	LEVETIRACETAM - AER
2013-2311	03/25/2013 04/22/2013	OC/OM/OMP/DDM/ OC/OM/OMP/DDM/	EAS CONSULTING GROUP LLC	DKT LOG 1990N-0200
2013-2312	03/25/2013 04/22/2013	OC/OM/OMP/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	DKT 1990N-0200
2013-2313	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (03/18/2013 - 03/22/2013)
2013-2314	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jerome Lew JEROME LEW	INFUSE BONE GRAFT - AERS, NON-COMPLIANCE OF IRB, RESPONSES ETC
2013-2315	03/26/2013 04/23/2013	ORA/ ORA/	Sarah Sellers q-Vigilance, LLC	MEDI-FARE PHARMACY - 483 (12/01/2012 - 01/31/2013)
2013-2316	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Camilla Recke BioPorto Diagnostics A/S	K953239
2013-2317	03/26/2013 04/23/2013	ORA/ ORA/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Richard O. Wood the Wood Burditt group	97Y-0007131-4/1-1 (STERILE NON-ADHERENT PAD 2 X 3), 97Y-0007131-4/2-1 (STERILE NON-ADHERENT PAD 3 X 4), 97Y-0007131-4/16-1 (DK T-DRAIN SPONGE ECO 4X4 6PLY ST 2/PK 25PK/TY 12TY/CS)
2013-2318	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith Smith Associates	K982901
2013-2319	03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	E.J. Smith	K983716

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	04/23/2013		Smith Associates	
2013-2320	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2013-218
2013-2321	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ni Sun Alkermes, Inc.	TECFIDERA - SBA
2013-2322	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Saagar Patel Whitney Medical Solutions	K032065, K050322, K052395
2013-2323	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Buehler TEI Biosciences Inc.	RAW DATA TO SUPPORT ADVERSE EVENT TABLE
2013-2324	03/26/2013 04/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alvin Washington Alvin Washington	CYTOMEL - AERS
2013-2325	03/26/2013 04/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Timothy Joy RMC Pharmaceutical Solutions, Inc	SYNCO BIO PARTNERS VC, AMSTERDAM - 483, EIR, RESPONSE (04/01/2012 - 03/01/2013)
2013-2326	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1581 REQUEST LETTER
2013-2327	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1265 - REQUEST LETTER
2013-2328	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1224 REQUEST LETTER
2013-2329	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-960 REQUEST LETTER
2013-2330	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS HODGSON RUSS LLP	PRISMATIK DENTALCRAFT INC - OBSIDIAN CERAMIC BLOCKS K100781
2013-2331	03/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY L GOERSS	IVOCAR USA INC - HIGH GOLD PALLADIUM FREE

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	04/23/2013		HODGSON RUSS LLP	CERAMIC SOLDER K012877
2013-2332	03/26/2013 04/23/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	GILBERT R WEINER ADVANCED PHARMA CR LLC	CETERO RESEARCH - EIR 2007
2013-2333	03/26/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ ORA/ ORA/ ORA/OE/ ORA/OE/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ANTHONY M ELEFTHERI LEWIS WAGNER LLC	CHAMBERLAIN FARMS INC, OWENSVILLE, IN - SALMONELLA OUTBREAK INSPS, 483S, NOTES, RECALL RECS, ETC 2012
2013-2334	03/26/2013 04/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE AND PERINDOPRIL - AERS 12/7/12 TO PRESENT
2013-2335	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	ZIEBOL, LOIS	CONCENTRIC MEDICAL INC - CONCENTRIC BALLOON GUIDE CATHETER K112404
2013-2336	03/26/2013 04/23/2013	FDA/OF/CFSAN/OCD/EOS/	BECKY COOSEMAN BROWN & CROUPPEN PC	CRONOBACTER INVESTIGATIONS - LAB W/S, EPIDEMIOLOGY FILES, DENDROGRAMS, ETC 2009 TO 2012
2013-2337	03/26/2013 04/23/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ ORA/OE/ ORA/OE/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	PATRICK N BROYLES BROYLES LAW FIRM	ZIMMER - FITMORE HIP STEM DESIGN CHANGES, PACKAGING, CLEARANCE FOR MARKETING, ETC
2013-2338	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ ORA/OE/ ORA/OE/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	PATRICK N BROYLES BROYLES LAW FIRM	ZIMMER - POROLOCK MIS STEM K071723 INSTRUCTIONS FOR USE, CLEARANCE FOR MARKETING, WARNINGS, ETC

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2013-2339	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - RIATA, RIATA ST DEFIBRILLATOR LEADS CORPORATE QUALITY SYSTEM IMPROVEMENT PLANT (QSIP), CORPORATE QSIP STEERING COMMITTEE, ETC ATTACHMENTS, EXHIBITS, MINS, ETC
2013-2340	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - UPDATE TO 483 9/3/09, EXHIBITS, ATTACHMENTS, RECS, ETC
2013-2341	03/26/2013 04/23/2013	FDA/OF/CFSAN/OCD/EOS/	MITCHELL A CHEESEMAN PHD STEPTOE & JOHNSON	ECOLAB INC - FAP 2A4785 RVW MEMO
2013-2342	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OO/OHR/	DUNCAN, HILARIO R	ANNOUNCEMENT PH-NM-13-764407 SUPERVISORY PARALEGAL SPECIALIST - CORR
2013-2343	03/26/2013 04/23/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	JOHN WALSH JAMES ALEXANDER CORP	HALTERMANN, HOUSTON, TX - EIRS, 483S, PROD RECALLS
2013-2344	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	CENTERVUE SPA - MAIA MODEL 1 K092187
2013-2345	03/26/2013 04/23/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	DOMINGO, VANESSA	COLORADO BIOLABS INC - EIR MOST RECENT
2013-2346	03/26/2013 04/23/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	HOWARD SCHWARTZ, MIAMI RES ASSOC, MIAMI, FL - 483S 10/05 TO PRESENT
2013-2347	03/26/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MITCHELL, ERIC	ONE LAMBDA INC - MICROSSP HLA KIT BK960062
2013-2348	03/26/2013 04/23/2013	FDA/OGROP/ORAPA-FO/LOS- DO/LOS-CB/	ERNIE MOLINA AMERICOLOR CORP	AMERICOLOR CORP, PLACENTIA, CA - EIR, 483 9/13/12
2013-2349	03/26/2013 04/23/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 138930, 139159, 140919, ETC
2013-2350	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K955433
2013-2351	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K974295
2013-2352	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF	K942315

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			TECHNOLOGY	
2013-2353	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K896087
2013-2354	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K895041
2013-2355	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K092886
2013-2356	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K113576
2013-2357	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K771219
2013-2358	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K051522
2013-2359	03/26/2013 04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	OLIVE O'DRISCOLL CORK INSTITUTE OF TECHNOLOGY	K000801
2013-2360	03/26/2013 04/23/2013	FDA/OC/OES/DFOI/	MITCHELL A CHEESEMAN PHD STEPTOE & JOHNSON	2010-763, 2009-9561
2013-2361	03/27/2013 04/24/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Dale Misczynski Monebo Technologies, Inc.	MONEBO, AUSTIN, TX - MTG RECS (12/10/2012 - 12/30/2012)
2013-2362	03/27/2013 04/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tom Burton WALL STREET JOURNAL	AFFYMAX INC - ANAYLSES, MEMOS, LETTERS RE ADVERSE EVENTS (02/01/2013 - 03/26/2013)
2013-2363	03/27/2013 04/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OO/OHR/ ORA/ ORA/ ORA/	Doe J	INDIVIDUAL RECS

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		ORA/		
2013-2364	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jodi Kimble ProMedTek, Inc.	K083433
2013-2365	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Buck Brown iScreen Vision	PEDIAVISION INC SPOT VS100 - INVESTIGATION RECS
2013-2366	03/27/2013 04/24/2013	FDA/OC/OES/	Geoffrey R Chambers Geoffrey R. Chambers	FDA MEETING RE PATIENT-CENTRIC PROVISIONS OF FDASIA - MINUTES
2013-2367	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K032097
2013-2368	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies Inc.	K020885
2013-2369	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Srividya Sukadev Pan Medical	K122533
2013-2370	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Srividya Sukadev Pan Medical	K981251
2013-2371	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-889 REQUEST LETTER
2013-2372	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-884 - REQUEST LETTER
2013-2373	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1561 REQUEST LETTER
2013-2374	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1288 REQUEST LETTER
2013-2375	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-847 REQUEST LETTER
2013-2376	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2010-8135
2013-2377	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mr. Katsuhiko Baba (New Business Strategy Group) SEIKO EPSON CORPORATION	K093981
2013-2378	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Yu-Ju Chiang Chung Yuan Christian University	K013434, K093192, K982707
2013-2379	03/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim	K101438

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	04/24/2013		Ellipse Technologies, Inc.	
2013-2380	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jodi Kimble ProMedTek, Inc.	K022458
2013-2381	03/27/2013 04/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Karen Griffin HOSPIRA INC	D-096-2013 - HHE, RISK ASSESSMENT
2013-2382	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen Griffin Hospira, Inc.	Z-0069-2013 - HHE, RISK ASSESSMENT
2013-2383	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	LEVINE, AMY L	SMITH & NEPHEW, BIRMINGHAM, AL - HIP RESURFACING DVC P04033 POST APRVL STUDY PROTOCOL, PROGRESS RPTS, STATUS DETERMINATION, ETC
2013-2384	03/27/2013 04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ OC/OM/OMP/DDM/ FDA/OC/OES/DDM/	DINGLE, DAN	CPG 305.100 ACUPUNCTURE DVC & ACCESSORIES, DKT 94P-0443, ANESTHESIOLOGY DVC ADVISORY PANEL MEETING, 6/15/76, 3/22/78, 10/1/80, ETC
2013-2385	03/27/2013 04/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GREGORY B BREDLOVE CUNNINGHAM BOUNDS ET AL	AZULFINDE(SUFASALAZINE) APLASTIC ANEMIA- AERS LAST 20 YRS
2013-2386	03/27/2013 04/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ANN M CARVALHO McLarens Global Claim Services	SNYER'S LANCE, COLUMBUS, GA - EIRS 2011, 9/2012, 10/2012
2013-2387	03/27/2013 04/24/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	CHRISTOPHER M KANE SIMON GLUCK & KANE LLP	MITIGATION GUIDELINES - VIOLATIONS
2013-2388	03/27/2013 04/24/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON	HERBALIFE INTERNATIONAL - INVESTIGATION, ENFORCEMENT ACTION, COMPLIANCE ACTION 5/1/12 TO 3/22/13
2013-2389	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	DONALD E SEGAL ALSTON & BIRD LLP	CRYOLLIFE INC, KENNESAW, GA - EIRS, 483S, WARNING LTRS, ETC 1/13 TO PRESENT
2013-2390	03/27/2013 04/24/2013	ORA/ ORA/ ORA/ORO/ ORA/ORO/ FDA/OGROP/ORA/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORTS UNDER USFDA OVERSIGHT - 20130325-1 1/13 TO PRESENT

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2013-2391	03/27/2013 04/24/2013	ORA/ ORA/ ORA/ORO/ ORA/ORO/ FDA/OGROP/ORA/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORTS UNDER USFDA OVERSIGHT - 20130325-2 1/1/11-12/31/11
2013-2392	03/27/2013 04/24/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-1908
2013-2393	03/27/2013 04/24/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/ FDA/OMPT/CTP/OD/	CATHERINE MACRUM HUGHES HUBBARD & REED	INITATION WITH MENTHOL CIGARETTES & YOUTH SMOKING UPTAKE - SUMM, RPTS, CORR, ETC FINAL RPT 11/10
2013-2394	03/27/2013 04/24/2013	FDA/OF/CFSAN/OCD/EOS/	MICHELLE LEVINSON NATURAL RESOURCES DEFENSE COUNCIL	PRIORITY BASED ASSESSMENT OF FOOD ADDITIVES (PAFA) DATABASE - RECS
2013-2395	03/28/2013 04/25/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Joce Sterman WMAR/ABC-2	AMERICAN CRUISE LINES - INSPECTION REPORTS (01/01/2008 - 03/01/2013)
2013-2396	03/28/2013 04/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DDM/	Darwin Tandam Neutraderm, Inc	UNDECYLENIC ACID - CLINICAL DATA FOR NAIL FUNGUS TREATMENT
2013-2397	03/28/2013 04/25/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Robert Blaskiewicz Robert Blaskiewicz	STANISLAW BURZYNSKI, HOUSTON, TX - 483 (01/01/2013 - 04/01/2013)
2013-2398	03/28/2013 04/25/2013	FDA/OF/CFSAN/OCD/EOS/	Haruya Kato Kato Business Consulting	BASF - UNTITLED LETTER RECS (02/06/2007 - 03/26/2013)
2013-2399	03/28/2013 04/25/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Mark Fenton TAKEDA PHARMACEUTICALS NORTH AMERICA INC	AMERISOURCE BERGEN, SACRAMENTO, CA - 483 (01/01/2012 - 12/31/2012)
2013-2400	03/28/2013 04/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	ANDRODERM - INITIAL APPROVAL RECS
2013-2401	03/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim	K100312

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	04/25/2013		Ellipse Technologies, Inc.	
2013-2402	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K971783
2013-2403	03/28/2013 04/25/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Shawn Stoley All American Foods, Inc.	SAMPLE RESULTS AND REPORT
2013-2404	03/28/2013 04/25/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Felix Briaud Camicas Productions	RONALD ANDIO DBA PATRON FARMS LLC - WARNING LETTER FOLLOW UP RECS (07/09/2012 - 07/09/2012)
2013-2405	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K980854
2013-2406	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Buck, Ph.D., Esq. Pribanic & Pribanic, L.L.C.	NEURONTIN - APPROVAL LETTER
2013-2407	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Valerie Franck STRYKER INSTRUMENTS	K123188
2013-2408	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	REQUIP NDA 20658/S13 - MEDICAL OFFICER RVW
2013-2409	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K040485
2013-2410	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K030286
2013-2411	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ashley Driscoll Diazyme Laboratories	K121232
2013-2412	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Donald Barry MEDICA CORPORATION	K022158
2013-2413	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K102971
2013-2414	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melanie Bell Scilucent, LLC	PERTZYE - SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2415	03/28/2013 04/25/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	CRESCENDO THERAPEUTICS LLC, VISTA, CA - EIRS, 483S, CO RESP 4/11
2013-2416	03/28/2013 04/25/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENENTECH INC - EIRS, 483S, CO RESP 8/12
2013-2417	03/28/2013 04/25/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER INC - EIRS, 483S, CO RESP 12/12
2013-2418	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	XYLO CHEM INDUSTRIES, NADIAD, INDIA - EIRS, 483S, CO RESP 7/11
2013-2419	03/28/2013 05/09/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	ENZYME SOLUTIONS INC - EIRS, 483S, CO RESP 10/12
2013-2420	03/28/2013 04/25/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	DEXTRUM LABORATORIES INC - EIRS, 483S, CO RESP 7/12
2013-2421	03/28/2013 04/25/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERCK SHARPE & DOHME CORP, WEST POINT, PA - EIRS, 483S CO RESP 9/12
2013-2422	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LUPIN CHEMICALS, TARAPUR, INDIA - EIRS, 483S, CO RESP 6/12
2013-2423	03/28/2013 04/25/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, MARION, NC - EIRS, 483S, CO RESP 8/12
2013-2424	03/28/2013 04/25/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	LACLEDE INC, RANCHO DOMINGUEZ, CA - EIRS, 483S, CO RESP 6/19-27/12
2013-2425	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	JUBILANT HOLLISTERSTIER GENERAL PARTNERSHIP, KIRKLAND QUEBEC, CANADA - EIRS, 483S, CO RESP 3/19-26/12
2013-2426	03/28/2013	FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY	APOTEX INC, TORONTO, ON , CANADA - EIRS, 483S, CO

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	04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMSON REUTERS	RESP 8/13-24/12
2013-2427	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	CSL BEHRING, MARBURG, GERMANY - EIRS, 483S, CO RESP 1/27/12
2013-2428	03/28/2013 04/25/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA, ROCKY MOUNT, NC - EIRS, 483S, CO RESP 2/12/13-3/13/13
2013-2429	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL F. COLIN, M.D. FIRST MANHATTAN CO	DAIICHI SANKYO - BENICAR CORR
2013-2430	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL F. COLIN, M.D. FIRST MANHATTAN CO	NOVARTIS - DIOVAN CORR
2013-2431	03/28/2013 04/25/2013	FDA/OF/CFSAN/OCDE/EOS/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - SPEECH NUTRIENTS SPEAK CMLPTS
2013-2432	03/28/2013 04/25/2013	FDA/OF/CFSAN/OCDE/EOS/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - SUPPLEMENTS CMLPTS
2013-2433	03/28/2013 04/25/2013	FDA/OF/CFSAN/OCDE/EOS/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services, Inc.	FCN 141
2013-2434	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY Center for Regulatory Services, Inc.	UNTITLED CDRH LTRS FROM 1/12
2013-2435	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH L MARCHESE BURSOR & FISHER PA	ST JUDE MEDICAL INC - RIATA & RIATA ST MODEL 1560, 1561, 1562, ETC RECS
2013-2436	03/28/2013 04/25/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-	COURTNY GERRISH TODAYS TMJ4 WTMJ-TV	MEALS FOR FLIGHTS OUT OF MILWAUKEES MITCHELL INT'L AIPTORT & CHICAGO OHARE 1/4/10-12/2/12 - INSP; LSG SKY CHEFS & GATE GOURMET FACILITIES 1/4/10-12/28/12

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		DO/MIN-CB/		
2013-2437	03/28/2013 04/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALBERTINE LUGINBUHL LIBRAIRIE MEDI SCIENCES	RPT FSR FOR HO407G
2013-2438	03/28/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MITCHELL, ERIC	PEL FREEZE CLNCL SYS - UNITRAY SSP HLA TYPING KITS BK000019
2013-2439	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	LORI COHEN GREENBERG TRAUIG LLP	CR BARD INC - AVAULTA SUPPORT SYS; SOFRADIM PRODUCTION - UGYTEX DUAL KNIT MESH CORR
2013-2440	03/28/2013 04/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M. HOFFMEISTER WILSON SONSINI ET AL	LOESTRIN 24 FE ANDA 078-267 - APRVL
2013-2441	03/28/2013 04/25/2013	FDA/OF/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS ET AL	HERBALIFE LTD - INVESTIGATIONS 5/12 TO 3/22/13
2013-2442	03/28/2013 04/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ ORA/OCI/ ORA/OCI/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	DANIEL P. LAPINSKI WILENTZ GOLDMAN & SPITZER PA	RAM MEDICAL INC - COUNTERFEIT POLYPROPYLENE SURGICAL MESH PRODUCTS CORR
2013-2443	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melanie Bell Scilucent, LLC	ULTRESA - SBA
2013-2444	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Silverstein Sigma Capital Management	PML ETC - AERS
2013-2445	03/29/2013 04/26/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Matthew Wallace CARGILL	GILMAN FARM SERVICE CENTER - PHOTOS (03/22/2013 - 03/22/2013)
2013-2446	03/29/2013	FDA/OMPT/CDER/GRP/DIDP/	Jennifer Caggiano	OSP - WARNINGS (CERTIFIED)

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	04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sidney P. Cominsky Trial Lawyers LLC	
2013-2447	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mark Priz Registrar Corp	RADIATION EMITTING DEVICES REPORTED TO CDRH UNDER AN INITIAL RADIATION SAFETY REPORT (01/01/2008 - 12/31/2012)
2013-2448	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Casey A. Metzger STRYKER INSTRUMENTS	K972832
2013-2449	03/29/2013 04/26/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	KS ChetakSF	ENTRY 551-2353070-7
2013-2450	03/29/2013 04/26/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Stephen Willey Stifel Nicolaus & Co	ALEXION PHARMACEUTICALS, SMITHFIELD, RI - WARNING LETTER RECS
2013-2451	03/29/2013 07/31/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 939
2013-2452	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 78267 - APPROVAL, TENTATIVE APPROVAL
2013-2453	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Giles - Regulatory Specialist DenTek Oral Care, Inc.	K942633
2013-2454	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alan Brett Mindways Software, Inc.	K983273
2013-2455	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Charlie Mack IRC KOREA	K122120
2013-2456	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jenna Groves Genesis Biosystems, Inc.	K965256
2013-2457	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Giles DenTek Oral Care, Inc.	K964976
2013-2458	03/29/2013 04/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jenna Groves Genesis Biosystems, Inc.	K963204
2013-2459	03/29/2013 04/26/2013	ORA/ ORA/	RAVNITZKY, MICHAEL	GENERAL MILLS CORP - RECS

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2013-2460	03/29/2013 04/26/2013	ORA/OE/ ORA/OE/	ALISON YOUNG USA TODAY	DIETRARY SUPPLEMENTS - RECAL RECS
2013-2461	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	MITCHELL A GOLDSTEIN Babener & Associates	NU SKIN ENTERPRISES INC (PHARMANEX) - NANOCOQ10 CLAIMS NOTIFICATIONS
2013-2462	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M HOFFMEISTER WILSON SONSINI ET AL	ANDA 78-267 - APRVL TLR
2013-2463	03/29/2013 04/26/2013	FDA/OF/CFSAN/OCD/EOS/	TODD S STEWART TODD S STEWART LAW OFCS	PELICAN SEAFOOD CO, MACY'S SMOKED FISH & DIP LLC, FORT PIERCE, FL, ETC - CIGUATERA POISONING RECS, EIRS, ATTACHMENTS, ETC
2013-2464	03/29/2013 04/26/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	TODD BOWLUS HARRY S COHEN & ASSOCIATES PC	INDIVIDUAL RECS
2013-2465	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	ANCHEN PHARMACEUTICALS INC - LUVOX CR ANDA 91-476 APRVL LTR 3/13/13
2013-2466	03/29/2013 04/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	DIV OF BIOEQUIVALENCE GUIDANCE FOR IN VIVO BIOEQUIVALENCE STUDIES OF METAPROTERENOL SULFATE AND ALBUTEROL (METERED DOSE INHALERS)
2013-2467	03/29/2013 04/26/2013	CVM/OCD/	ADAM DIEDERICH SCHIFF HARDIN LLP	RESIDUE TESTING OF HORSES AND HORSE MEAT 1/1/11 TO PRESENT
2013-2468	03/29/2013 04/26/2013	FDA/OGROP/ORA/ORO/DIOP/	MAYA FOA REPRIEVE	SODIUM THIOPENTAL POWDER - IMPORTS 1/1/12 TO PRESENT
2013-2469	03/29/2013 04/26/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WANDA CARPINELLA NAVILYST MEDICAL	NAVILYST MEDICAL INC, MARLBOROUGH, MA - EIRS 9/16/11
2013-2470	03/29/2013 04/26/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WANDA CARPINELLA NAVILYST MEDICAL	NAVILYST MEDICAL INC, GLENS FALLS, NY - EIRS 9/8-21/09, 4/30/10-5/27/10, 7/5-11/11
2013-2471	03/29/2013	FDA/OGROP/ORA/PA-FO/SAN-		RHEIN BIOTECH GMBH, DUSSELDORF, GERMANY;

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	04/26/2013	DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHADLE, PAULA	DYNAVAX TECHNOLOGIES INC, BERKELEY, CA - EIRS, 483S 2012, CO RESP 2/25/13
2013-2472	03/29/2013 04/26/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ALEXION PHARMACEUTICALS INC, CHESHIRE, CT - EIRS, 483S, WARNING LTRS, ETC 1/1/11 TO PRESENT
2013-2473	04/01/2013 04/29/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	Merritt Lentz Lentz, Earl M	MOTIONS PROFESSIONAL HAIR RELAXER REGULAR - CONSUMER COMPLAINTS, ADVERSE EVENTS, INVESTIGATIONS ETC
2013-2474	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mihir Taneja Belcher Pharmaceuticals, LLC	NDA 005897, NDA 006135, NDA 006012 ETC
2013-2475	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Cano Agile Therapeutics	QUARTETTE - MEDICAL OFFICER REVIEW, SUMMARY REVIEW
2013-2476	04/01/2013 04/29/2013	FDA/OF/CFSAN/OCD/EOS/	Cambria Roth Insight Magazine	PESTICIDE TESTS - FRUITS AND VEGETABLES
2013-2477	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sarah Buduson WEWS - NewsChannel5	MIRENA - AERS
2013-2478	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Indeep Aulak Response Point of Care Inc.	K021317, K030286, K042890 ETC
2013-2479	04/01/2013 04/29/2013	FDA/OF/CFSAN/OCD/EOS/	Amy Taylor Infotrieve, Inc	PATHOLOGY REPORT ON OSBORNE-MENDEL RATS FED PHENETHYL SENOCIOATE IN RATIONS FOR FOUR MONTHS

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2013-2480	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deb Hubers Deb Hubers	CYANOCOBALAMIN INJECTION USP 1000 MCG/ML - APPROVAL RECS
2013-2481	04/01/2013 04/29/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Tanisha Breton Tanisha Breton	PETAG - DATA, LAB RESULTS, COMMUNICATIONS ETC (01/01/2009 - 03/28/2013)
2013-2482	04/01/2013 04/29/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Melissa Stillson Stillson, Melissa	SWEET P'S COOKIES - COMPLAINT RECS (11/01/2012 - 01/01/2013)
2013-2483	04/01/2013 04/29/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shin Kang WELLS FARGO SECURITIES	ALEXION PHARMACEUTICALS - 483, RESPONSE LETTERS, WARNING LETTER (08/01/2012 - 03/28/2013)
2013-2484	04/01/2013 04/29/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OC/OES/DFOI/	Patrick Moriarty HEALTHCOR MANAGEMENT LP	ALEXION PHARMACEUTICALS - WARNING LETTER, 483, COMMUNICATIONS, ETC (03/06/2009 - 03/28/2013)
2013-2485	04/01/2013 04/29/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Kumaraguru Raja Citi Research	ALEXION PHARMACEUTICALS - WARNING LETTER, 483 (08/06/2012 - 03/28/2013)
2013-2486	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - METAL ON METAL ACETABULAR SYS K993438
2013-2487	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A MAGNUM SYS K042037
2013-2488	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A MAGNUM 12/14 TAPER INSERTS & ONE-PIECE MODULAR HEADS K061423
2013-2489	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A 32MM TAPER SYS K003363
2013-2490	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A-MAGNUM TRI-SPIKE ACETABULAR COMPONENT K062995
2013-2491	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A C2A ACETABULAR SYS KK042841
2013-2492	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A ACETABULAR SYS K011110
2013-2493	04/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON	BIOMET INC - METAL-ON-METAL HIP SYS K113271

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	04/29/2013		ANDREWS & THORNTON	
2013-2494	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - TAPERLOC 12/14 TAPER FEMORAL COMPONENTS K042537
2013-2495	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - M2A 28MM RINGLOC ACETABULAR LINER K002379
2013-2496	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	GERALD R KOLB BENDCABLE	LIST OF CERTIFIED MAMMOGRAPHY SITES UNDER THE MAMMOGRAPHY QUALITY STANDARDS ACT (MQSA) AS OF MOST RECENT DATE AVAILABLE
2013-2497	04/01/2013 04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	BIOMET INC - METAL-ON-METAL HIP SYS EXPANDED CONTRAINDICATIONS K082446
2013-2498	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	ZHEJIANG XIANJU PHARMS, ZHEJIANG, CHINA - 483S 7/18-21/11
2013-2499	04/01/2013 04/29/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2010-3861, 2010-3977, 2010-4021, ETC
2013-2500	04/01/2013 04/29/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-2179, 2012-2188, 2012-2685, ETC
2013-2501	04/01/2013 04/29/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-339, 2013-876, 2013-159, ETC
2013-2502	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHRIS CANO Agile Therapeutics	TEVA - QUARTETTE (LEVNORGESTREL/ETHINYL ESTRADIOL & ESTRADIOL) TABS MEDICAL OFFICERS RVWS, SUMMARY RVWS
2013-2503	04/01/2013 04/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	EDWARD R MCNICHOLAS SIDLEY AUSTIN LLP	VIFOR PHARMA LTD - IRON SUCROSE ANDA 78-215 APRVL RECS, PUBLIC LOG RECEIPT
2013-2504	04/01/2013 04/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	MEADE, DORIS .	S & S FLAVORS, ST BREA, CA - EIR; 2/11
2013-2505	04/01/2013 04/29/2013	ORA/ ORA/ ORA/ORM/ ORA/ORM/	ROBERT KING FDA NEWS	LIST OF 483S NOTICES OF INSPECTIONAL OBSERVATIONS FOR PHARMACEUTICALS, BIOLOGICS & MEDICAL DVC MFG FACILITIES IN THE USA & OUTSIDE OF THE USA 2/1-28/13

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2013-2506	04/01/2013 04/29/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Doe J	CMPLNT - TOMATO PASTE
2013-2507	04/01/2013 04/29/2013	CVM/OCD/	Doe J	CMPLNT - PURINA BENEFULL DOG FOOD
2013-2508	04/01/2013 04/29/2013	OC/OM/OMP/DDM/	SETH MAILHOT SHEPPARD MULLIN	DKT 1995S-0316
2013-2509	04/01/2013 04/29/2013	OC/OM/OMP/DDM/	LYNN DITTIDRAI GIBSON DUNN & CRUTCHER LLP	FDC-70 DKT LOG, FDC-77 TR, EXHIBITS
2013-2510	04/02/2013 04/30/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	LUO, LUCY	CMPLNT 131355
2013-2511	04/02/2013 04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS M. BURTON WALL STREET JOURNAL	IN VITRO DIAGNOSTICS - AERS
2013-2512	04/02/2013 04/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE JAMES, ND Sound Sleep Health	ATTIX - HCG AER
2013-2513	04/02/2013 04/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHY M. McGOWN FOKKISER	QUARTETTE (LEVONORGESTREL/ETHINYL ESTRADIOL) NDA 204-061 SBA
2013-2514	04/02/2013 04/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAZARES, MARCUS .	DAVROCET - BAN
2013-2515	04/02/2013 04/30/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	ALEXION PHARMACEUTICALS INC, CHESHIRE, CT; SWITZERLAND; RI - 483, EIR, WARNING LTR, UNTITLED LTRS 1/11 TO PRESENT

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2013-2516	04/02/2013 04/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN F. THOMPSON, PHARM D, FCP ROBINSON & THOMPSON	PROPYLTHIOURACIL - AER
2013-2517	04/02/2013 04/30/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	PATRICIA L. REGENYE Celgene Corporation	CHERIAN VERGHESE, ALBERT EINSTEIN MED CTR, PHILADELPHIA, PA - 483 2/07 TO 3/13
2013-2518	04/02/2013 04/30/2013	CVM/OCD/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	DEB WINKLER PUTNEY INC	PFIZER ANIMAL HEALTH, LINCOLN NE; BAYER HEALTHCARE LLC; SHAWNEE, KS; BAYER, JOSEPH, MO - 483 MOST RECENT
2013-2519	04/02/2013 04/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HOLLY EMRICK SVETZ WOMBLE CARLYLE ET AL	SHIRE DEVELOPMENT INC - PROAMATINE CORR
2013-2520	04/02/2013 04/30/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ ORA/ ORA/	GENEVIEVE M. SPIRES PORZIO BROMBERG & NEWMAN PC	WELCHS FOODS INC - FRUIT SNACK 5/11 TO 6/11
2013-2521	04/02/2013 04/30/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DAVID A. CHAPPELLE NFI DISTRIBUTION	NFI DISTRIBUTION, TAMPA, FL - EIR 2/27/13
2013-2522	04/02/2013 04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	STRYKER SUSTAINABILITY SOLUTIONS - REPROCESSED STEERABLE INTRODUCER K123334
2013-2523	04/02/2013 04/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	LUCA VESCOVO PARAMED SRL	MR OPEN K101295
2013-2524	04/02/2013 04/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANA CABRERA KMGH-TV	PHYSICIANS, PHARMACIES SEEKING PERMISSION TO USE HGH PAST 10 YRS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-2525	04/02/2013 04/30/2013	FDA/OC/OES/DFOI/	MARIA STISO PREMIER INVESTIGATORS	DANIELE INT'L V. WHOLESOME SPICE & SEASONINGS - SALMONELLA 2009
2013-2526	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BETH ZIEMBA CELL THERAPEUTICS INC	RUXOLITINIB - MEDWATCH 3500A
2013-2527	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JAMES F SWINDOLL JAMES F SWINDOLL LAW OFCS	CLARIS LIFESCIENCE, CLARIS LIFESCIENCE INC - IV METRONIDAZOLE RECALL RECS
2013-2528	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elspeth Callahan INDEPENDENCE LEGAL SUPPORT	AUGUST 2007 LETTER TO PALATIN TECHNOLOGIES RE BREMELANOTIDE; CLINICAL TRIAL DATA
2013-2529	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OM/OMP/DDM/ FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ABUK IMPURITIES IN OXYCODONE HCI PRODUCTS
2013-2530	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	ANCHEN PHARMACEUTICALS INC - LUVOX CR ANDA 91-476 APRVL LTR 3/13/13
2013-2531	04/03/2013 05/01/2013	FDA/OMPT/CTP/OD/ OC/OL/ FDA/OMPT/CTP/OD/	MARK GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	CENTER FOR TOBACCO PRODUCTS MTG - REQUIREMENTS FOR TESTING OF HARMFUL CONSTITUENTS REQUIRED BY SECTION 904 OF THE TOBACCO CONTROL ACT
2013-2532	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SIDNEY WOLFE MD PUBLIC CITIZEN	ISRS 6865332, 7031713, 7031715, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2533	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - SOLYX SIS SYS K081275 CMLPTS, 510K CLEARANCE
2013-2534	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - ADVANTAGE TRANSVAGINAL MID URETHRAL SLING SYS K020110 CMLPTS, 510K CLEARANCE, ETC
2013-2535	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - PINNACLE PELVIC FLOOR REPAIR KITS K071957 CMLPTS, 510K CLEARANCE, ETC
2013-2536	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - PREFYX PPS SYS K040787 CMLPTS, 510K CLEARANCE, ETC
2013-2537	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - ADVANTAGE FIT SYS K020110 CMLPTS, 510K CLEARANCE, ETC
2013-2538	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - LYNX SUPRAPUBIC MID URETHRAL SLING SYS K020110 CMLPTS, 510K CLEARANCE, ETC
2013-2539	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - UPHOLD VAGINAL SUPPORT SYS K081048 CMLPTS, 510K CLEARANCE, ETC
2013-2540	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - OBTRYX TRANSOBTURATOR MID URETHRAL SLING SYS K040787 CMLPTS, 510K CLEARANCE, ETC
2013-2541	04/03/2013 05/01/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Benjamin Essner crossover Healthcare Fund	MEETING TRANSCRIPTS
2013-2542	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr. C. J. Kaiser gke-GmbH	K113302
2013-2543	04/03/2013 05/01/2013	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS (02/26/2013 - 03/29/2013)
2013-2544	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Newman JMP Securities	NDA 204063
2013-2545	04/03/2013 05/01/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Ken Reid Washington Information Source Co.	ALEXION PHARMACEUTICALS, RHODE ISLAND - 483, EIR, RESPONSE (08/02/2012 - 03/29/2013)
2013-2546	04/03/2013 05/01/2013	ORA/ ORA/	James A. Robson Cash, Krugler & Fredericks LLC	CLINICAL SPECIALTIES LLC AKA CLINICAL SPECIALTIES COMPOUNDING PHARMACY - RECALL RECS MARCH 2013

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2013-2547	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Newman JMP Securities	NDA 202379 S005
2013-2548	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	ANDA 77415
2013-2549	04/03/2013 05/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	William Hite Columbia Management	ALEXION - WARNING LETTER (03/27/2013 - 03/28/2013)
2013-2550	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	ASR TAPER SLEEVE ADAPTER SIZE 12/14+2 - RPTS, CORR, RECALL RECS, ETC
2013-2551	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Silverstein Sigma Capital Management	ISR 8917306, 9191334, 9126116
2013-2552	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	DEPUY - ASR XL ACETABULAR SYS RPTS, CORR, RECALL RECS, ETC
2013-2553	04/03/2013 05/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Chris Wubbolt QACV Consulting, LLC	AMERICAN DENTAL PARTNERS, INC, WAKEFIELD, MA - EIR (1/31/2013 - 3/29/2013)
2013-2554	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daan De Coster Department of Primary Care and Population Health, University College London	INHALED BECLOMETHASONE, BECLOMETASONE - DRUG MARKETING AUTHORIZATIONS
2013-2555	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mathijs de Vaan Columbia University	QUARTERLY DATA FILES FROM AERS
2013-2556	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	DEPUY - ASR ACETABULAR CUP RPTS, CORR, RECALL RECS, ETC

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2013-2557	04/03/2013 05/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	JONATHAN KLEIN SULLIVAN & COLLINS LLC	DEPUY - ASR UNI FEMORAL IMPLANT RPTS, CORR, RECALL RECS, ETC
2013-2558	04/03/2013 05/01/2013	FDA/OF/CFSAN/OCD/EOS/	BRIAN H ELDRIDGE Segal McCambridge Singer & Mahoney	NUTRICIA NORTH AMERICA INC - NEOCATE E028 SPLASH CAERS, Cmplnts, TESTING, ETC
2013-2559	04/03/2013 05/01/2013	FDA/OF/CFSAN/OCD/EOS/	BRIAN H ELDRIDGE Segal McCambridge Singer & Mahoney	NUTRICIA NORTH AMERICA INC - NEOCATE JUNIOR CAERS, Cmplnts, TESTING, ETC
2013-2560	04/03/2013 05/01/2013	FDA/OF/CFSAN/OCD/EOS/	BRIAN H ELDRIDGE Segal McCambridge Singer & Mahoney	NUTRICIA NORTH AMERICA INC - NEOCATE INFANT RPTS, CORR, RECALL RECS, ETC
2013-2561	04/03/2013 05/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK - SINGULAIR (MONTELUKAST) ISRS 4660916, 7509835
2013-2562	04/03/2013 05/01/2013	FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	FOI DAILY LOG 3/25-29/13
2013-2563	04/03/2013 05/01/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	O'NEILL, KIT	NEW DAY FISHERIES INC - EIR, CLOSEOUT LTR, CO RESP, ETC 2004 TO PRESENT
2013-2564	04/04/2013 05/02/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT FDA-2012-P-1103
2013-2565	04/04/2013 05/02/2013	OC/OM/OMP/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	DKT 1978N-1520, OTC VOL 060024, ETC.
2013-2566	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	(Mr) Taro Kanai (First Name/Last Name) MIC International Corp.	K121622
2013-2567	04/04/2013 05/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OM/OMP/DDM/ FDA/OC/OES/DDM/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	DRAFT GUIDANCE ON BUPROPRION HYDROCHLORIDE - ADMIN FILE
2013-2568	04/04/2013	FDA/OGROP/ORA/NE-FO/NWE-	Alethia Young	ALEXION - 483 ASSOCIATED WITH MARCH 27, 2013 483

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	05/02/2013	DO/NWE-CB/	DEUTSCHE BANK	
2013-2569	04/04/2013 05/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Leckerman; Marcel Pratt BALLARD SPAHR LLP	FDA FINDING THAT BUDEPRION XL 300 MG WAS NOT THERAPEUTICALLY EQUIVALENT TO WELBUTRIN XL 300 MG
2013-2570	04/04/2013 05/02/2013	OC/OM/OMP/DDM/ FDA/OC/OES/DDM/	William Miller DepuySynthes	GENERAL AND PLASTIC SURGERY DEVICES PANEL OF THE MEDICAL DEVICE ADVISORY COMMITTEE - MTG MINUTES RE DOWN CLASSIFICATION OF PET SUTURES ; FEDERAL REGISTER
2013-2571	04/04/2013 05/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chloe Bird PROFESSIONAL COMPOUNDING CENTERS OF AMERICA (PCAA)	LIST OF FOREIGN IMPORTED DRUG PRODUCTS; LISTING OF NDC NUMBERS (01/03/2012 - 04/02/2013)
2013-2572	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kathryn A. Jayne SomnoMed, Inc.	K050592
2013-2573	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS 3/1-31/13
2013-2574	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 3/31/13
2013-2575	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K122154
2013-2576	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K092435
2013-2577	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K081359
2013-2578	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K052611
2013-2579	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K003469
2013-2580	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT	K012141

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			ENGINEERING	
2013-2581	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K020857
2013-2582	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K021340
2013-2583	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K030532
2013-2584	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K030587
2013-2585	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K033617
2013-2586	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K033657
2013-2587	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	DREW HILL STAGE 2 CONTRACT ENGINEERING	K050172
2013-2588	04/04/2013 05/02/2013	FDA/OC/OES/DFOI/	MARY STIPANCIC PHARMA MEDICA RESEARCH INC	COVANCE INC, MADISON, WA - EIRS, 483S
2013-2589	04/04/2013 05/02/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	K MICHELLE VASSALLO LINCARE INC	ON DEMAND HOME MEDICAL LLC, OH - EIRS, 483S, WARNING LTRS, ETC 1/05 TO PRESENT
2013-2590	04/04/2013 05/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY SMITH	PONATINIB/ICLUSIG - AERS
2013-2591	04/04/2013 05/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/	Sakal, John	ALBUTEROL - TEST RESULT 2/3/12

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		ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ ORA/OCI/ ORA/OCI/		
2013-2592	04/04/2013 05/02/2013	FDA/OF/CFSAN/OCD/EOS/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	SYNGENTA SEEDS INC - BNF 95
2013-2593	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MARY K BLASY Robbins, Geller, Rudman & Dowd	VENTRUS - VEN 309 (IFERANSERIN OINTMENT) - COMM, RPTS, INTERNAL RECS
2013-2594	04/04/2013 05/02/2013	FDA/OF/CFSAN/OCD/EOS/	LISA M RAVE WHYTE, HIRSHBOECK AND DUDEK, S.C.	QUALITYEGG LLC, GALT, IA - CORR 1/1/10 TO 12/31/11
2013-2595	04/04/2013 05/02/2013	FDA/OF/CFSAN/OCD/EOS/	MATEA GOLD LOS ANGELES TIMES	INTERAGENCY WORKING GROUP - FOOD MARKETED TO CHILDREN CORR, EMAILS, COMM
2013-2596	04/04/2013 05/02/2013	FDA/OF/CFSAN/OCD/EOS/	R CRAIG MCLAUGHIN ELK & ELK	RIVER RANCH FRESH FOODS PRODUCTS - LISTERIA EIRS, PHOTOGRAPHS, VIDEOTAPES, ETC
2013-2597	04/04/2013 05/02/2013	OC/OM/OMP/DDM/	GLORIA GASKINS KLEINFELD KAPLAN & BECKER	DKT 2002P-0435
2013-2598	04/04/2013 05/02/2013	FDA/OMPT/CDRH/OCER/DFOI/	tom watkins CNN	INSULIN PUMP MALFUNCTIONS, INCENTIVES TO PRESCRIBE
2013-2599	04/04/2013 05/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ortav Yehudai Great Point Partners, LLC	CAMBREX PROFARMACO MILANO, MILAN, PAULLO, IT - 483 (04/03/2012 - 04/01/2013)
2013-2600	04/05/2013 05/03/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Chris Elam Diabetes OneStop	DR SHERWYN L SCHWARTZ, SAN ANTONIO, TX - 483, RESPONSES, LETTERS (01/27/1995 - 08/31/2009)
2013-2601	04/05/2013 05/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tracie Carey, Regulatory Program Director Roche TCRC, Inc.	ISR 5662103, 4490357, 6410825 ETC
2013-2602	04/05/2013 05/03/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Brienne Kugler Morgan Stanley	ALEXION - WARNING LETTER, 483

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2013-2603	04/05/2013 05/03/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Blake C. Arnold Robert W. Baird & Co.	ALEXION PHARMACEUTICALS - 483, RESPONSE (08/01/2012 - 12/25/2012)
2013-2604	04/05/2013 05/03/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Emily Bartkowicz AKERMAN SENTERFITT ATTYS	SURGICAL MESH - CORR, MEDICAL LITERATURE, INSPECTION RECS, ETC
2013-2605	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Debbie Cabrera Agile Therapeutics	QUARTETTE - MEDICAL OFFICER REVIEW AND SUMMARY REVIEW
2013-2606	04/05/2013 05/03/2013	ORA/ ORA/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jeff Pecoraro Pecoraro, Jeffery A	INDIVIDUAL RECS
2013-2607	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 3/4-8/13
2013-2608	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HAYNES, JANE ISBELL	FORTEO - AERS 2000 TO 4/3/13
2013-2609	04/05/2013 05/03/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WILLIAM SLEVIN NORTH AMERICAN RESCUE LLC	H&H ASSOCIATES INC, ORDINARY, VA - EIRS, 483S 2012 MOST RECENT
2013-2610	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK - KC 200, KC300 FACE MASK K111402
2013-2611	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	H DAVID BLAIR BLAIR & STROUD ATTYS	SMITH & NEPHEW - R3 ACETABULAR SYS K083566
2013-2612	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	AMY KINCANON LEXISNEXIS COURTLINK INC	2011-7417
2013-2613	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	PRODUCT CODE ONB - CLOSED ANTINEOPLASTIC AND HAZARDOUS DRUG RECONSTITUTION AND TRANSFER SYSTEMS

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2013-2614	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACOB MCDOWELL WEINBERG GROUP INC	ABBOTT - HUMIRA BLA 125057 APRVL LTR, FINAL LBLG, MOR, ETC
2013-2615	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID PENG PHD Stifel Nicolaus & Co	ARIAD PHARMS - ICLUSIG CLNCL TRIALS RECS
2013-2616	04/05/2013 05/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS J MOORE INSTITUTE FOR SAFE MEDICATION PRACTICES	ETRAVIRINE, RILONACEPT, DESVENLAFAXINE, ETC - NDA'S 22-187, NDA 12-5249, NDA 21-992POSTMARKETING COMMITMENTS, ETC
2013-2617	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	SAMUEL FRIEDMAN SAMUEL FRIEDMAN ATTORNEY AT LAW	2009-4918, 2009-9429 (CERTIFIED)
2013-2618	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	DEPUY INC - ZIRCONIA ARTICUL/EZE FEMORAL BALLS K952088
2013-2619	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	BIOMET INC - FREEDOM CONSTRAINED LINERS K030047
2013-2620	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	BIOMET INC - FULL HEMISPHERE RINGLOC LINER K920640
2013-2621	04/05/2013 05/03/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JOHN A BERANBAUM BERANBAUM MENKEN LLP	LTR TO NEW YORK DOWONTOWN HOSPITAL 8/12
2013-2622	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL ENDOSCOPIC INSTRUMENT CONTROL SYS K090993
2013-2623	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL DA VINCI SI SURGICAL SYS - K081137
2013-2624	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL DA VINCI ENDOSCOPIC INSTRUMENTS, CONTROL SYS & ENDOWRIST STABILIZER K080291

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2013-2625	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	INTUITIVE SURGICAL DA VINCI SINGLE SITE INSTRUMENTS & ACCESSORIES K112208
2013-2626	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	BIOMET INC - SHP HIP SYS K960984
2013-2627	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MODIFICATION TO INTUITIVE SURGICAL DA VINCI SURGICAL SYS & ENDOSCOPIC INSTRUMENTS - K043288
2013-2628	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	DEPUY INC - ULTIMA METAL-ON-METAL ACETABULAR CUP K001523
2013-2629	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	DEPUY INC - ULTIMA UNIPOLAR HEAD AND ADAPTER SLEEVES K965156
2013-2630	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	JOINT MEDICAL PRODUCTS CORP - ZTT I AND II ACETABULAR CUP OF THE S-ROM TOTAL HIP SYS K951000
2013-2631	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DDM/	JOHN C THORNTON ESQ ANDREWS & THORNTON	MCKEE-FARRAR METAL-ON-METAL HIP - RECS
2013-2632	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	RING METAL-ON-METAL HIP - RECS
2013-2633	04/05/2013 05/03/2013	OC/OM/OMP/DDM/	LAUREN FAMIGGIA Hyman, Phelps & McNamara, P.C.	DKT FDA-2009-N-0205, FDA-2010-N-0475, ETC.
2013-2634	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	SIVASH METAL-ON-METAL TOTAL HIP PROTHESES - RECS
2013-2635	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	SULZER ORTHOPEDICS INC - INTER-OP METASUL ACETABULAR SYS K974728
2013-2636	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	WRIGHT MEDICAL TECHNOLOGY INC - CONSERVE PLUS SPIKED SHELL AND CONSERVE TOTAL 56MM FEMORAL HEAD K031963
2013-2637	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS THORNTON	WRIGHT MEDICAL TECHNOLOGY INC - METAL TRANSCEND ARTICULATION SYS K004043
2013-2638	04/05/2013 05/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C THORNTON ESQ ANDREWS & THORNTON	WRIGHT MEDICAL TECHNOLOGY INC - METAL TRANSCEND ARTICULATION SYS K021349
2013-2639	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	SMITH & NEPHEW INC - REFLECTION CERAMIC

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	05/03/2013		ANDREWS & THORNTON	ACETABULAR SYS -P030022
2013-2640	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	ENCORE ORTHOPEDICS INC - FOUNDATION POROUS COATED FLARED RIM ACETABULAR CUP K974095
	05/03/2013	FDA/OC/OES/DFOI/	ANDREWS & THORNTON	
2013-2641	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	ENCORE ORTHOPEDICS INC - FOUNDATION POROUS COATED HEMISPHERICAL ACETABULAR K974093
	05/03/2013	FDA/OC/OES/DFOI/	ANDREWS THORNTON	
		FDA/OC/OES/DFOI/		
		FDA/OC/OES/DFOI/		
2013-2642	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	ENCORE ORTHOPEDICS INC - FMP METAL/METAL ACETABULAR INSERT K003250
	05/03/2013	FDA/OC/OES/DFOI/	ANDREWS & THORNTON	
2013-2643	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	HOWMEDICAL OSTEONICS CORP - STRYKER MODULAR HIP SYS K071082
	05/03/2013		ANDREWS & THORNTON	
2013-2644	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	HOWMEDICA OSTEONICS CORP - REJUVENATE MODULAR STEM K081044
	05/03/2013		ANDREWS & THORNTON	
2013-2645	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	HOWMEDICA OSTEONICS CORP - ABG II MODULAR HIP STEM K092406
	05/03/2013	FDA/OC/OES/DFOI/	ANDREWS & THORNTON	
2013-2646	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	ZIMMER GMBH - DUROM ACETABULAR COMPONENT AND METASUL LDH LARGE DIAMETER HEADS K053536
	05/03/2013	FDA/OC/OES/DFOI/	ANDREWS THORNTON	
		FDA/OC/OES/DFOI/		
		FDA/OC/OES/DFOI/		
2013-2647	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	CENTERPULSE ORTHOPEDICS INC - EPSILON METASUL ACETABULAR INSERT AND METASUL MODULAR FEMORAL HEAD K033634
	05/03/2013	FDA/OC/OES/DFOI/	ANDREWS THORNTON	
		FDA/OC/OES/DFOI/		
		FDA/OC/OES/DFOI/		
2013-2648	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	BIOMET INC - UNIVERSAL ACETABULAR CUP, METAL ON METAL ACETABULAR SYS K993438
	05/03/2013		ANDREWS & THORNTON	
2013-2649	04/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C THORNTON ESQ	BIOMET INC - TITANIUM MULLER TOTAL HIP K780357
	05/03/2013		ANDREWS & THORNTON	
2013-2650	04/05/2013	FDA/OC/OES/DFOI/	KEN REID	FOI DAILY LOG 3/11-15/13
	05/03/2013		WASHINGTON INFORMATION SOURCE	
2013-2651	04/05/2013	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 3/4-8/13
	05/03/2013		DOMINION GROUP INC	
2013-2652	04/05/2013	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 3/11-15/13

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	05/03/2013		DOMINION GROUP INC	
2013-2653	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/4-8/13
2013-2654	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/4-8/13
2013-2655	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 3/11-15/13
2013-2656	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 3/11-15/13
2013-2657	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 3/11-15/13
2013-2658	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/4-8/13
2013-2659	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 3/11-15/13
2013-2660	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 3/4-8/13
2013-2661	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 3/11-15/13
2013-2662	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/11-15/13
2013-2663	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 3/4-8/13
2013-2664	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/4-8/13
2013-2665	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 3/11-15/13
2013-2666	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 3/4-8/13
2013-2667	04/05/2013	FDA/OC/OES/DFOI/	LAUREN S BARR	CLOSED FOIA REQUESTS 3/11-15/13

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	05/03/2013		JH BARR & ASSOCIATES LLC	
2013-2668	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 3/4-8/13
2013-2669	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOFIF DAILY LOG 3/11-15/13
2013-2670	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 3/4-8/13
2013-2671	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 3/11-15/13
2013-2672	04/05/2013 05/03/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA WEBVIEW/FERDID	CLOSED FOIA REQUESTS 3/4-8/13
2013-2673	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ingrid Hoos HORIZON PHARMA INC	NDA 202020
2013-2674	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trupti Shah TAKEDA PHARMACEUTICALS NA INC	OMONTYS - AERS
2013-2675	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Corridan Alden Medical LLC	K892329
2013-2676	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dion Brandt TIDI Products, LLC	K953672
2013-2677	04/08/2013 05/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Donald Parriott County College of Morris	USER GUIDE FOR CBER'S ELECTRONIC SIGNATURE PROCESS
2013-2678	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jacquelin M. Cronin Jacobi & Chamberlain LLP	KLONOPIN - WARNINGS, LABELS, APPLICATIONS ETC
2013-2679	04/08/2013 05/06/2013	FDA/OC/OES/DFOI/	Desmond Jenson Public Health Law Center	CTP FOIA REQUEST LOG
2013-2680	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph T. Shen, MD Premier Heart, LLC	K992703

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2013-2681	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARTER GOULD JMP Securities	ICLUSIG - ARES
2013-2682	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	KLONIPIN - AERS
2013-2683	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Carl Jenkins WOOD BURDITT GROUP	K110131
2013-2684	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gene Hall Gene Hall	DMF 15062
2013-2685	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue Elevate Oral Care	K945794
2013-2686	04/08/2013 05/06/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	NOVARTIS CONSUMER HEALTH INC, LINCOLN, NE - EIR (01/21/2013 - 02/28/2013)
2013-2687	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mihir Zaveri UC Berkeley Graduate School of Journalism	K083191; K923367; K831949 ETC
2013-2688	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue Elevate Oral Care	K102808
2013-2689	04/08/2013 05/06/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Angela Turner Turner, Angela	NOVARTIS CONSUMER HEALTHCARE INC, LINCOLN, NE - RESPONSE TO 483 MARCH 2013
2013-2690	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sigal Melamed-Gal Teva Pharmaceuticals Company	PRILOSEC - SBA
2013-2691	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Maryann Vigliotta Annovation Biopharma	AMIDATE - SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2692	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Aleq Rojas Aleqtro Global, L.L.C.	K994095
2013-2693	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Garry Pogil Law Office of Garry Pogil	TRAVATAN - AERS
2013-2694	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	shin kang WELLS FARGO	JAKAFI - AERS
2013-2695	04/08/2013 05/06/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Mitchell A. Goldstein Babener & Associates	NU SKIN ENTERPRISES AKA PHARMANEX - COMM WITH FDA RE NANOCOQ10
2013-2696	04/08/2013 05/06/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Pradeepan Srinivasan Yem Foods LLC	ENTRY 11279475193 - REPORT OF PESTICIDE ANALYSIS
2013-2697	04/08/2013 05/06/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Healthy Life Purity First Healthy Life Purity First	HEALTHY LIFE PURITY FIRST - COMPLAINTS
2013-2698	04/08/2013 05/06/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OL/	Eric Lipton THE NEW YORK TIMES	HEMISPHERX BIOPHARMA (01/01/2012 - 06/01/2013) - CORR OUTSIDE NDA PROCESS
2013-2699	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	EMILY KRISTEN STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	INRANGE REMOTE MEDICATION MANAGEMENT SYS K051338
2013-2700	04/08/2013 05/06/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/ FDA/OF/CFSAN/OCD/EOS/	EASLEY 103481, KENT A	PHENYLKETONURICS - RECS
2013-2701	04/08/2013	FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUWATTAR	MYLAN PHARMS INC - ACYCLOVIR OINTMENT ANDA 202-

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	05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REDDY'S LABORATORIES INC	459 CHEMISTRY RVW
2013-2702	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARYLEE LAWREY WATSON LABORATORIES INC	CINDAMYCIN CAPS ANDA 63-083, PROBENECID TABS ANDA 84-442, CORTICOTROPIN INK ANDA 88-772 - BIO SECTION
2013-2703	04/08/2013 05/06/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Doe J	INDIVIDUAL RECS
2013-2704	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTINE JAMES ND Sound Sleep Health	ATTIX - HCG AERS
2013-2705	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH CODED AS MEDICATION ERROS 3/1-31/13
2013-2706	04/08/2013 05/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOAN STITT (UG2CD-16) MERCK & CO., INC.	MERCK - ISENTRESS (RALTEGRAVIR) ISRS 7234397, 8365298
2013-2707	04/08/2013 05/06/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK S JAFFE JAFFE LAW FRIM	DR HENRY LIN - INVESTIGATION RECS, VIOLATIONS REFERENCED IN WARNING LTR 3/8/10, STATUS OF ENFORCEMENT PROCEEDINGS, ETC
2013-2708	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY PAGNOZZI SMC DIRECT LLC	HENRY SCHEIN - ONE STEP+ HCG TEST K953988; IMMUNOCARD STAT! - HCG COMBO ADVANTAGE PREGNACY TEST K9992187
2013-2709	04/08/2013 05/06/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	WALMART - CORR MENTIONING GMO, GENETICALLY MODIFIED, LBLG, ETC
2013-2710	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MUNA KEA TECHNOLOGIES - CELLVIZIO 100 SERIES, CELLVIZIO SYSTEMS WITH CONFOCAL MINIPROBES K122042

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2013-2711	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MUNA KEA TECHNOLOGIES - CELLVIZIO 100 SERIES SYS, CELLVIZIO SYS WITH CONFOCAL MINIPROBES K120208
2013-2712	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	MUNA KEA TECHNOLOGIES - CELLVIZIO 100 SERIES SYS WITH CONFOCAL MINPROBES K111047
2013-2713	04/08/2013 05/06/2013	FDA/OF/CFSAN/OCD/EOS/	FOI Services, Inc.	EASTMAN CHEMICAL CO - FCN 1041
2013-2714	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	FOI Services, Inc.	PENTAX MEDICAL CO - CONFOCAL VIDEO COLONOSCOPE K042741
2013-2715	04/08/2013 05/06/2013	CVM/OCD/	FOI Services, Inc.	ELANCO ANIMAL HEALTH - TYPE B AND TYPE C REGULATORY ASSAY METHODS FOR TYLAN (TYLOSIN PHOSPHATE) NADA 12-491
2013-2716	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	BIOGEN IDEC - TECFIDERA (DIMETHYL FUMARATE) N204063
2013-2717	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - BIO MOORE ENDO HEADS K984028
2013-2718	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - CFE TOTAL HIP FEMORAL COMPONENT K830313
2013-2719	04/08/2013 05/06/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	TRUDY FLOURNOY STEPTOE & JOHNSON	2011-6947
2013-2720	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - METAL ACETABULAR SYS K993438
2013-2721	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - NON CEMENTED POROUS COATED TOTAL HIP PROSTHESES K030055
2013-2722	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - PF ACETABULAR COMPONENT K861114
2013-2723	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - MALLORY HEAD TOTAL HIP SYS K853259
2013-2724	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - TAPERLOC FEMEROL STEM & UNIVERSAL ACETABULAR COMPONENT K921301
2013-2725	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	DEPUY INC - FOCUS TOTAL HIP SYS K883460
2013-2726	04/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq.	DEPUY INC - ARTICUL EZE FEMORAL HEADS K980513

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	05/06/2013		ANDREWS & THORNTON	
2013-2727	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - HYDROXYAPATITE COATED REFLECTION ACETABULAR SHELL & HA COATED REFLECTION INTERFIT SHELL K990666
2013-2728	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION ACETABULAR COMPONENT K932755
2013-2729	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - MODULAR ACETABULAR CUP SYS K920430
2013-2730	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - RELECTION 3 ACETABULAR SYS K070756
2013-2731	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION 3 ACETABULAR SYS K061253
2013-2732	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SMITH & NEPHEW INC - REFLECTION DUAL DIMENSION SHELL K960094
2013-2733	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SULZER ORTHOPEDICS INC - INTER OP DURASUL ACETABULAR INSERT K983509
2013-2734	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	SULZER ORTHOPEDICS INC - INTER OP DURASUL ACETABULAR INSERTS & COCR FEMORAL HEADS K993259
2013-2735	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOHN C. THORNTON, Esq. ANDREWS & THORNTON	BIOMET INC - BIO MOORE ENDO HEAD TAPER ADAPTER K002106
2013-2736	04/08/2013 05/06/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - CMLPTS
2013-2737	04/08/2013 05/06/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	NOURISH LIFE LLC - SPEECH NUTRIENTS CMLPTS
2013-2738	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOWZE, BRITTANY	PROJECTS CONDUCTED BY DR JACQUELINE LEUNG, UCSF MEDICAL CTR 5R01AG031795 - 04, 5R01AG031795-03, 5R01AG031795-02
2013-2739	04/08/2013 05/06/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDANEWS	483 NOTICES FOR PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC, CLNCL TRIAL FACILITIES 3/13
2013-2740	04/08/2013 05/06/2013	OM/OSS/OPILS/FDAHO/ FDA/OC/OES/DFOI/	ALISON YOUNG USA TODAY	REUMOFAN - DOCS

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2013-2741	04/08/2013 05/06/2013	FDA/OO/OFBA/OAGS/	PATRICK CHENG CHILDRENS NATIONAL MEDICAL CENTER	MICHIGAN PEDIATRIC DVC CONSORTIUM, ANN ARBOR, MI; MISTRAL DVC CONSORTIUM, MENLO PK, NJ; PEDIATRIC CARDIOVASCULAR DVC CONSORTIUM, BOSTON, MA ETC - 2009 TO 2012
2013-2742	04/08/2013 05/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CATHY PETTERSEN MULLIN LAW GROUP PLLC	TRI SPRINTEC - AER
2013-2743	04/08/2013 05/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS S. MURPHY ANDOVER HEALTHCARE INC	MEDICAL PRODS INACCURATELY LABELED AS LATEX FREE - RECS
2013-2744	04/08/2013 05/06/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Jim Strickland WSB-TV	NESTLE PURINA PETCARE, FAIRBURN, GA - 483 (01/03/2010 - 04/03/2013)
2013-2745	04/08/2013 05/06/2013	FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/OIP/	Derick Lucas AGILENT TECHNOLOGIES	CHEMICAL CONTAMINANTS IN FOOD FROM FOREIGN POSTS
2013-2746	04/09/2013 05/07/2013	OC/OM/OMP/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	OTC VOL. 060030, 060031, ETC.
2013-2747	04/09/2013 05/07/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ OC/OCC/	ANN WATERHOUSE HILL-ROM	HILL-ROM, MICHAEL MURPHY MTG - TRANS 3/28/13
2013-2748	04/09/2013 05/07/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Doe J	INDIVIDUAL RECS
2013-2749	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PHARMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S0101 CORR, MINS, AMENDMENTS, ETC
2013-2750	04/09/2013 05/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PHARMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S009 AMENDMENTS, WARNINGS, CORR, ETC
2013-2751	04/09/2013	FDA/OMPT/CDER/ORP/DIDP/	ERIC H WEINBERG	BOEHRINGER INGELHEM PHARMACEUTICAL INC -

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	05/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERIC H WEINBERG ESQ	PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S007 AMENDMENTS, CORR, MINS, ETC
2013-2752	04/09/2013 05/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ERIC H WEINBERG ERIC H WEINBERG ESQ	BOEHRINGER INGELHEM PAHRMACEUTICAL INC - PRADAXA (DABIGATRAN ETEXILATE MESYLATE) NDA 22-512/S005 RISK EVALUATION AND MITIGATION STRATEGY (REMS), CORR, MINS, ETC
2013-2753	04/09/2013 05/07/2013	FDA/OC/OES/DFOI/	ANN WATERHOUSE HILL-ROM	HILL-ROM, BATESVILLE, IN - 483 2/1/13
2013-2754	04/09/2013 05/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GHORMLEY 138287, ANTHONY	VISTARIL - AERS
2013-2755	04/09/2013 05/07/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OF/CFSAN/OCD/EOS/	VALERIE HANNIG OPPENHEIMER GROUP	COMPANIES LISTING DAVID OPPENHEIMER, OPPENHEIMER GROUP AS US AGENT (FRUIT & VEGETABLE IMPORTER)
2013-2756	04/09/2013 05/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AUBAGIO - AERS
2013-2757	04/09/2013 05/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ENBREL BLA 103795 - APRVL RECS, MEDICAL RVWS
2013-2758	04/09/2013 05/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL F COLIN MD FIRST MANHATTAN CO	VIVUS INC - QSYMIA AERS 9/15/12 TO PRESENT
2013-2759	04/09/2013 05/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARK PRINZ Registrar Corp	LIST OF FOREIGN RADIATION EMITING DVC MFRS 1/08 TO 12/12
2013-2760	04/09/2013 05/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICHELLE BODIEN QUIDEL CORPORATION	CLINICAL INNOVATIONS LLC - ROM PLUS AND ROM PLUS CONTROLS K110605

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2013-2761	04/09/2013 05/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHELLE BODIEN QUIDEL CORPORATION	METRIKA INC - DRX QT HCG & DRX QT HCG CONTROL SET K991532
2013-2762	04/09/2013 05/07/2013	FDA/OC/OES/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5-HOUR ENERGY; PEPSICO INC - AMP ENERGY; FUZE BEVERAGE LLC - FULL THROTTLE, ETC OFFICE OF THE COMMISSIONER CORR 2/1/13 TO PRESENT
2013-2763	04/09/2013 05/07/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5-HOUR ENERGY; PEPSICO INC - AMP ENERGY; FUZE BEVERAGE - FULL THROTTLE, ETC CENTER FOR FOOD SAFETY AND APPLIED NUTRITION CORR 2/1/13
2013-2764	04/09/2013 05/07/2013	OC/OL/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5-HOUR ENERGY; PEPSICO INC - AMP ENERGY; FUZE BEVERAGE - FULL THROTTLE, ETC - OFFICE OF LEGISLATION CORR 2/1/13
2013-2765	04/09/2013 05/07/2013	FDA/OF/CFSAN/OCD/EOS/	Steven Burman Steven Burman	HAIR DYE INDUSTRY CONSENT AGREEMENT
2013-2766	04/10/2013 05/08/2013	OC/OM/OMP/DDM/	MARILYNN WHITNEY COVINGTON BURLING LLP	DKT & DKT LOG OF 1996N-0082
2013-2767	04/10/2013 05/08/2013	FDA/OGROP/ORR/SE-FO/ATL-DO/ATL-CB/	JONATHAN CARLSON WNCN-TV	FOOD FACILITY INSPS AT AIRLINE CATERING FACILITIES AT RALEIGH DURHAM INTERNATIONAL AIRPORT, MORRISVILLE, NC - RECS 1/11 TO 4/13
2013-2768	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	CARRIE WELCH RN DICKINSON PRUD'HOMME ADAMS & INGRAM LLP	MDRS 1847269, 1847254, 1068225, ETC 1/1/08 TO 4/1/13
2013-2769	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRIS DIMITROPOULOS ELION INVESTMENTS	ISIS PHARMS - SMNRX PRE-IND MTG MINS
2013-2770	04/10/2013 05/08/2013	FDA/OGROP/ORR/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALIA, PARMINDER SINGH	VERITAS HEALTHCARE LLC, NY - CLNCL INVESTIGATOR LIST, FINANCIAL DISCLOSURE STATEMENT, HIPAA AUTHORIZATION, ETC PRIOR TO 10/14/11
2013-2771	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K IVERSON COHEN & GRIGSBY PC	MEDTRONIC - THORACIC STENT GRAFT SYS P070007 CORR, APRVL LTRS, LBLG, ETC
2013-2772	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	JEFFREY J JONES JONES DAY	SCOTTS COMPANY LLC, GUTWEIN & CO INC - WILD BIRD FOOD PRODS FOI REQUESTS 1/08 TO PRESENT

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2013-2773	04/10/2013 05/08/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ ORA/OE/ ORA/OE/	JOSH LONG VIRGO PUBLISHING	DIETARY SUPPLEMENT FACILITIES - 483S, WARNING LTRS, ENFORCEMENT ACTIONS, ETC FY 2010 TO FY 2012
2013-2774	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALAN R BENNETT ESQ ROPES & GRAY LLP	SUN PHARMA GLOBAL FZE - DOXORUBICIN HYDROCHLORIDE LIPOSOME INJ ANDA 203-263 REVIEWER MEMO
2013-2775	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOCELYN J IVERSON NIELSEN ZEHE & ANTAS PC	AGFA CORP - DRYSTAR 4500M IMAGER MDRS
2013-2776	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ruby Holder Greywall Asset Management	ADO-TRASTUZUMAB EMTANSINE - AERS
2013-2777	04/10/2013 05/08/2013	CVM/OCD/	JEANNIE PERRON COVINGTON & BURLING LLP	PHYTASE USE IN ANIMAL FEED - SAFETY ASSESSMENT
2013-2778	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nathan Sadeghi-Nejad Palkon Capital Management	ICLUSIG - AERS
2013-2779	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Piette Durrance UNC Chapel Hill	FDA APPROVED EMERGENCY CONTRACEPTIVES - NDC CODES
2013-2780	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ruby Holder Greywall Asset Management	PONATINIB HYDROCHLORIDE (ICLUSIG) - AERS
2013-2781	04/10/2013 05/08/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/OCI/ ORA/OCI/ FDA/OMPT/CDER/GRP/DIDP/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON LLP	CARL ICAHN, ICAHN ENTERPRISES, ICAHN PARTNERS, ICAHN & CO - INVESTIGATION RECS, ENFORCEMENT ACTIONS 5/1/12 TO 3/22/13

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2013-2782	04/10/2013 05/08/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Kevin P. Farrell WILSON ELSE ET AL	APHENA PHARMA SOLUTIONS MARYLAND FNA CELESTE CONTRACT PACKAGING, EASTON, MD - INVESTIGATIONS, INSPECTIONS, ENFORCEMENT ETC (04/01/2009 - 04/01/2013)
2013-2783	04/10/2013 05/08/2013	FDA/OF/CFSAN/OCD/EOS/	Dayun Ko Ko, Dayun	FCN 475
2013-2784	04/10/2013 05/08/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/OCI/ ORA/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON LLP	ROBERT CHAPMAN, CHAPMAN CAPITAL - INVESTIGATION RECS, ENFORCEMENT ACTION, COMPLIANCE ACTION 5/1/12 TO 3/22/13
2013-2785	04/10/2013 05/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Veronika Pesheva Pesheva, Veronika	ANTHRAX VACCINE IMMUNIZATION PROGRAM FOR MILITARY UNITS - PROTOCOLS
2013-2786	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vassilios Christodouloupoulos SANDOZ CANADA INC.	NDA 203168
2013-2787	04/10/2013 05/08/2013	CVM/OCD/	Dena White Boehringer Ingelheim Vetmedica, Inc.	NADA 009505, NADA 098379, NADA 140856 ETC - FOI SUMMARIES
2013-2788	04/10/2013 05/08/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/OCI/ ORA/OCI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	UDI GROFMAN PAUL WEISS RIFKIND WHARTON & GARRISON LLP	DANIEL S LOEB, THIRD POINT LLC - INVESTIGATION RECS, ENFORCEMENT ACTION, COMPLIANCE ACTION 5/1/12 TO 3/22/13

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2013-2789	04/10/2013 05/08/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Lesley Valle Boehringer Ingelheim	JOHN DIPERSIO, WASHINGTON UNIVERSITY SCHOOL OF MEDICINE, ST LOUIS, MO - 483 (01/01/1983 - 04/09/2013)
2013-2790	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Reckless Salix Pharmaceuticals, Inc.	NDA 203634
2013-2791	04/10/2013 05/08/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Jason Tsai KPC Products, Inc.	ENTRY FS2-1098058-7
2013-2792	04/10/2013 05/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Chris Elam Diabetes and Glandular Disease Clinic	DR MARK KIPNES, SAN ANTONIO, TX - 483 1998, 2000, 2012
2013-2793	04/10/2013 05/08/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Lesley Valle Boehringer Ingelheim	MD ANDERSON CANCER CENTER, HOUSTON, TX - 483 (01/01/1981 - 04/08/2013)
2013-2794	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Monica Reckless Salix Pharmaceuticals, Inc.	NDA 203634 - PHARMACOLOGY REVIEW
2013-2795	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	MATTHEW PEARLMAN PCMG INC	LIST OF FDA PURCHASE CARD HOLDERS
2013-2796	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DUSTIN BLOCK IPD ANALYTICS LLC	ETHINYL ESTRADIOL, NORETHINDRONE ACETATE ANDA 78-267 APRVL 9/1/09; ZOLEDRONIC ACID ANDA 91-363, ANDA 201-801 EFFECTIVE APRVL LTR 3/29/13
2013-2797	04/10/2013 05/08/2013	FDA/OF/CFSAN/OCD/EOS/	JAMES BLOOM NORM BLOOM & SON LLC	PROGRAM ELEMENT EVALUATION RPT OF GROWING AREA CLASSIFICATION ELEMENT FOR CT, PROGRAM ELEMENT EVALUATION RPT OF THE PLANT AND SHIPPING COR CT, ANNUAL PROGRAM EVALUATION RPT FOR CT FY 2006 TO FY 2012
2013-2798	04/10/2013 05/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHWETA PATEL HETERO USA INC	BENICAR (OLMESARTAN MEDOXOMIL TABS - LBLG
2013-2799	04/10/2013	FDA/OC/OES/DFOI/	JULIA G YOUNG	DAVOL INC - MESH COMPOSIX KUGEL PATCH RPTS

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	05/08/2013		STRICK LAW FIRM PLLC	
2013-2800	04/10/2013 05/08/2013	FDA/OO/OHR/	SANTORI, AGNES M	INDIVIDUAL RECS
2013-2801	04/10/2013 05/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEVE SCHIEFER COMPASS MOLDED PRODUCTS LLC	ROTONICS MFG - SHARPS PLUS 5 GALLON PLUS CONTAINER K980179
2013-2802	04/10/2013 05/08/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	KRISTEN CULTRARA DIETRICH LAW FIRM PC	FARM RICH (RICH FOODS) - RECALL RECS
2013-2803	04/10/2013 05/08/2013	FDA/OC/OES/DFOI/	Abraham, Troy	OPERATION MIND CONTROL - RECS
2013-2804	04/10/2013 05/08/2013	CVM/OCD/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	NICOLE A VENO IZARD NOBEL LLP	NESTLE PURINA PETCARE CO - BENEFUL BRAND DOG FOOD MYOTOXINS TEST SPLS 318110-0, 318111-0, 318112-0, ETC ANALYTICAL W/S, CORR
2013-2805	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	deborah gross Lympha Press USA	K120972
2013-2806	04/11/2013 05/09/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OF/CFSAN/OCD/EOS/	Cyndi Ivy Professional Liability Insurance Services, Inc.	SUNLAND, INC RAW AND ROASTED PEANUTS - RECALL RECS (09/14/2012 - 04/09/2013)
2013-2807	04/11/2013 05/09/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	roland@treeoflifeherbals.com Tree of Life Herbals	NATURAL WELLNESS LLC - STRUCTURE/FUNCTION CLAIMS UNDER DSHEA
2013-2808	04/11/2013 05/09/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	roland@treeoflifeherbals.com Tree of Life Herbals	LIFES2GOOD INC - STRUCTURE/FUNCTION CLAIMS UNDER DSHEA
2013-2809	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Vikas Gokhale BIO-Pace Technology Inc	SSD FOR PACEMAKERS VIGOR-DR, BROMOS-DR

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2013-2810	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sunil Patel Livwel Therapeutics Inc.	DRUG MASTER FILES 14327, 17411
2013-2811	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Virginia Beakes-Read Eisai Inc.	FDA/HHS RECOMMENDATION OF SCHEDULING UNDER THE CONTROLLED SUBSTANCES ACT SENT TO DEA RE FYCOMA TABLETS
2013-2812	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Jeffrey Dupont Iron Workers	SIBLEY MEMORIAL HOSPITAL, WASHINGTON, DC - EIRS (09/18/2009 - 07/15/2011)
2013-2813	04/11/2013 05/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO	DRUGS GRANTED BREAKTHROUGH THERAPIES (10/01/2012 - 04/09/2013)
2013-2814	04/11/2013 05/09/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	MaryAnn Ivie COSGRAVE VERGEER KESTER LLP	INVACARE CORPORATION - INSPECTIONS, WARNING LETTERS, TESTING ETC (04/01/2004 - 04/01/2012)
2013-2815	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	PEGINISATIDE - ANAPHYLAXIS OR HYPERSENSITIVITY
2013-2816	04/11/2013 05/09/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	EX-LAX, INC, HUMACAO, PR - EIR MOST RECENT (03/05/2013 - 03/07/2013)
2013-2817	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Skadden - Steven Napolitano Skadden, Arps, Slate, Meagher & Flom LLP	ANDA 074843
2013-2818	04/11/2013 06/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jonathan R. Sanford Nanobiosym Diagnostics, Inc.	BK030033

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2013-2819	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Hughes Dianna Hughes	GLYBURIDE - AERS
2013-2820	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	WELCHOL - OCP REVIEW OF DDI STUDIES
2013-2821	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Corey Pugliese Purcell & Ingrao	SOTRADECOL - AERS
2013-2822	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Timothy Bassett Pura Vida Investments	DELZICOL - REVIEW RECS (03/10/2011 - 02/10/2013)
2013-2823	04/11/2013 05/09/2013	FDA/OF/CFSAN/OCD/EOS/	Jeannette Cooperman St. Louis Magazine	SIMPLY THICK - FIRST COMMUNICATION RE POSSIBLE PROBLEM
2013-2824	04/11/2013 06/03/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Lesley Valle Boehringer Ingelheim	UNIVERSITY OF MICHIGAN, SOUTHWEST ONCOLOGY GROUP - 483 (01/01/1981 - 04/10/2013)
2013-2825	04/11/2013 05/09/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Laurence Paskowitz Paskowitz Law Firm P.C.	HOSPIRA, LAKE FOREST, IL; CLAYTON, NC; ROCKY MOUNT, NC ETC - EIRS (01/01/2009 - 04/10/2013)
2013-2826	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Skadden - Steven Napolitano Skadden, Arps, Slate, Meagher & Flom LLP	ANDA 040507
2013-2827	04/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA	P12005

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	05/09/2013		BIOTEX INC	
2013-2828	04/11/2013 05/09/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Eve Damiano Damiano Consulting Associates	SCIENTIFIC PROTEIN LABORATORIES, LLC, WAUNAKEE, WI - EIRS
2013-2829	04/11/2013 05/09/2013	FDA/OC/OES/DFOI/	CHRIS HURLEY COAST TO COAST	LIST OF FDA PURCHASE CARD HOLDERS
2013-2830	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Eli Werner GE MEDICAL SYSTEMS ISRAEL, FUNCTIONAL IMAGING	K082588
2013-2831	04/11/2013 05/09/2013	FDA/OF/CFSAN/OCD/EOS/	Ron Leisner PPG Industries, Inc.	FCN 1060
2013-2832	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	P050012
2013-2833	04/11/2013 06/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Jonathan R. Sanford Nanobiosym Diagnostics, Inc.	BK000038
2013-2834	04/11/2013 05/09/2013	FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2012-N-1032 - COMMENTS
2013-2835	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	ENBREL BLA 103-795/S1001 - CLNCL RVW
2013-2836	04/11/2013 05/09/2013	FDA/OC/OES/DDM/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	PSYCHOPHARMACOLOGIC DRUGS ADVISORY COMMITTEE - TRANSCRIPT (02/24/1984)
2013-2837	04/11/2013 05/09/2013	FDA/OF/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	DIETARY SUPPLEMENTS - CAERS 1/08 TO 12/31/12
2013-2838	04/11/2013 05/09/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BEIL, LAURA	CELLTEX THERAPEUTICS, HOUSTON, TX - CORR, EIRS, AERS
2013-2839	04/11/2013 05/09/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	VERONICA S KNAPP HOGAN LOVELLS US LLP	CANDY TREASURE LLC - CHOCO TREASURE EGGS SAFETY RECS
2013-2840	04/11/2013 05/09/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	LIST OF DOMESTIC & FOREIGN INSP FOR DRUG COMPANIES, MEDICAL DVC MANUFACTURERS, BIORESEARCH MONITORING ETC 2/13

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2013-2841	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	SANDRIL NDA 09-376, SERPANRAY NDA 09-391, SERPASIL NDA 09-115, ETC - APRVL LTR
2013-2842	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	RESERPINE - APRVL LTR
2013-2843	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R JOHNSON HOGAN LOVELLS US LLP	PHENDIMETRAZINE TARTRATE ER, 105MG PHENDIMETRAZINE TARTRATE CAPS - APRVL LTR
2013-2844	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HUTAR, CLAIRE	HUMAN EXPERIMENTS PERTAINING TO CONTRACEPTION 1/1900 TO 1/2000
2013-2845	04/11/2013 05/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IBRAHIM, ALEXANDRA	ISOTRETINOIN (ACUTANE) - AER
2013-2846	04/11/2013 05/09/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	MEADE, DORIS.	NATUREX, SHINGLE SPRINGS, CA - 483, EIR 12/17/12
2013-2847	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY & CO LTD, LACYTOWN, GUYANA - GINGERMINT BOZ-0018528-6 CERTIFIED
2013-2848	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY & CO LTD, LACYTOWN, GUYANA - CONFECTIONS 113-2105994-8 CERTIFIED
2013-2849	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - INDI CURRY POWDER DM9-3010657-8 CERTIFIED

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		DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/		
2013-2850	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - COUGH DROPS CANDY 406-0371077-9 CERTIFIED
2013-2851	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - TATTOO CHEWING GUM 406-0371007-9 CERTIFIED
2013-2852	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - GARAM MASALA 406-0443921-2 CERTIFIED
2013-2853	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY CO, LACYTOWN, GUYANA - CONFECTIONERY CONFECTIONS FOR CNSMPTION 916-2065571-1 CERTIFIED
2013-2854	04/11/2013 05/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMUEL FRIEDMAN, PC SAMUEL FRIEDMAN ATTORNEY AT LAW	EDWARD B BEHARRY & CO LTD, LACYTOWN, GUYANA - COUGH DROPS BOZ-0018528-6 CERTIFIED
2013-2855	04/11/2013 05/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HEATHER BRADLEY EISAI INC	FYCOMPA (PERAMPANEL) NDA 202-834 10/22/12
2013-2856	04/11/2013 05/09/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	MEADE, DORIS. .	NATUREX, HACKENSACK, NJ - EIR, 483 5/17/12
2013-2857	04/11/2013 05/09/2013	FDA/OO/OHR/	BOB STEEVES DICKINSON'S FDA WEBVIEW	LIST OF FDA EMPLOYEES PAID WITH GOVT APPROPRIATIONS
2013-2858	04/11/2013 05/09/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	163394 - CAERS
2013-2859	04/11/2013	FDA/OF/CFSAN/OCD/EOS/	DEVON Wm. HILL	REVIEW OF THE SUMMARY OF TABLE OF TOXICITY STUDIES ON DEHT

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	05/09/2013		Keller and Heckman, LLP	
2013-2860	04/11/2013 05/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	P980022
2013-2861	04/11/2013 05/09/2013	FDA/OO/OFBA/OAGS/	BELLE NEUMANN AB SCIEX	SOLICITATION RFQ762600 - RESPONSE
2013-2862	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2863	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brady Johnson TULANE UNIVERSITY	K122356
2013-2864	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ian McClellan Oregon Health & Science University	CANAGLIFLOZIN - REVIEW PACKET
2013-2865	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2866	04/12/2013 05/10/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kacie Carroll RN Barr & Mudford LLP	INCREDIBLE BULK, XCELER8-DHB, MASS XTREME ETC - AERS
2013-2867	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ ORA/OE/ ORA/OE/	Pat Williams Newman & McIntosh, LLC	DEXTROAMPHETAMINE/AMPHETAMINE 20 MG TABLETS, BARR LABORATORIES - RECALL RECS
2013-2868	04/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	David M. Gottfried	CORR FROM ROBERT SKIP CUMMINS TO FDA RE

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	05/10/2013		Law Office of David M. Gottfried	CYBERONICS AND A VEGUS NERVE STIMULATION IMPLANTATION DEVICE 2004 - 04/30/2005
2013-2869	04/12/2013 05/10/2013	FDA/OC/OES/DDM/	Katherine Giannamore Law Office of Katherine Giannamore, P.A.	52 FR 8831
2013-2870	04/12/2013 05/10/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	CORR WITH FDA RE LETTER FROM RJ REYNOLDS TO ANN SIMONEAU AND BEVERLY CHERNAIK; FOLLOW UP MEETING (01/10/2012 - 04/10/2013)
2013-2871	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	HYDROCODONE - AERS
2013-2872	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Murphy LaserPointerSafety.com	LASER REGULATION AS DEMONSTRATION LASERS OR SLA
2013-2873	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Farruggia Hyman, Phelps & McNamara, P.C.	ANDA 090358 - SBA
2013-2874	04/12/2013 05/10/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Lesley Valle Boehringer Ingelheim	VANDERBILT UNIVERSITY - 483 (01/01/1984 - 04/11/2013)
2013-2875	04/12/2013 05/10/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Evelyn Robertson ORGANOGENESIS INC	PROPPER MANUFACTURING, LONG ISLAND CITY, NY - EIR (01/01/2012 - 04/11/2013)
2013-2876	04/12/2013 05/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Evelyn Robertson ORGANOGENESIS INC	AVANTOR PERFORMANCE MATERIALS, PARIS, KY - EIR (08/01/2012 - 01/11/2013)
2013-2877	04/12/2013 05/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Michael Tomsic WFAE, NPR station in Charlotte, N.C.	BAXTER PHARMACEUTICALS, NORTH CAROLINA - INSPECTION RECS, WARNING LETTERS, ENFORCEMENT ACTIONS (12/01/2012 - 04/11/2013)
2013-2878	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sammy Almashat MD Public Citizen Health Research Group (HRG)	LIRAGLUTIDE - 16 AERS
2013-2879	04/12/2013 05/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Franz-Josef Braun Meda Pharma GmbH & Co. KG	GLENMARK'S GENERIC OF ALDARA CREAM - THERAPEUTIC EQUIVALENCE STUDIES

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2013-2880	04/12/2013 05/10/2013	FDA/OF/CFSAN/OCD/EOS/	PRESCOTT PAULIN 300 BELOW INC	TUNGSTEN DISULFIDE - APRVL
2013-2881	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	SEAN BUNDY COCHLEAR AMERICAS	SOPHONO INC - OTOMAG BONE CONDUCTION HEARING SYS MODEL ALPHA1 S & M K102199
2013-2882	04/12/2013 05/10/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	CHEN, JOHN	SAMUEL CS CHANG, FINEMOST CORP, CERRITOS, CA - WARNING LTR, 483
2013-2883	04/12/2013 05/10/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	CHEN, JOHN	MAO L YANG, GM MANUFACTURING INC, GARDENA, CA - WARNING LTR, 483
2013-2884	04/12/2013 05/10/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	MANGEL, DAVID A	CMPLNT 124067
2013-2885	04/12/2013 05/10/2013	FDA/OO/OFBA/OAGS/	AMY TONG STRATEGI CONSULTING LLC	NETIMPACT STRATEGIES INC - CONTRACT #HHSF223201210029I
2013-2886	04/12/2013 05/10/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	K. MICHELLE VASSALLO LINCARE INC	LONGCAP DNS LLC, FL - EIR, 483, WARNING LTR 1/05 TO PRESENT
2013-2887	04/12/2013 05/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	JUDY F. GORDON CLINREG CONSULTING SERVICES INC	FPT FRESCO PHOSPHENE TONOMETER K991840
2013-2888	04/12/2013 05/10/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LAUREL KOESTER WAVELIGHT LASER TECHNOLOGIE AG	WAVELIGHT GMBH, PRESSATH, GERMANY - EIR 1/28-31/13
2013-2889	04/12/2013 05/10/2013	CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	WESTERN CHEMICAL INC - PARASITE S (FORMALIN) NADA 140-989 APRVL, RVWS
2013-2890	04/12/2013 05/10/2013	CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	ARGENT CHEMICAL LABS INC - PARACIDE F (FORMALIN) NADA 140-831 APRVL, RVWS
2013-2891	04/12/2013 05/10/2013	CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	NATCHEZ ANIMAL SUPPLY CO - FORMALIN F (FORMALIN) NADA 137-687 APRVL, RVWS
2013-2892	04/12/2013 05/10/2013	CVM/OCD/	MICHAEL J. SWEENEY DICKIE MCCAMEY & CHILCOTE	BL MITCHELL INC - FORMACIDE B (FORMALIN) NADA 200- 414 APRVL, RVWS
2013-2893	04/15/2013 05/13/2013	FDA/OO/OFBA/OAGS/	Terrence M OConnor #2 Terrence M OConnor	ORACLE - CONTRACTS RECS (01/01/2010 - 04/10/2013)
2013-2894	04/15/2013 05/13/2013	FDA/OO/OFBA/OAGS/	Terrence M OConnor #3Revised Terrence M OConnor	ORACLE - CONTRACT DEBRIEFING SUMMARIES (01/01/2010 - 04/10/2013)

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2013-2895	04/15/2013 05/13/2013	FDA/OO/OFBA/OAGS/	Terrence M OConnor #1 Terrence M OConnor	CORR BETWEEN FDA AND ORACLE RE FEDERAL BUSINESS SYSTEMS CORP, DLT-FBSC, SOLARIS ETC (01/01/2010 - 04/10/2013)
2013-2896	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Paul Farrell Greene Ketchum	MEDICAL DEVICES WITH 510K CLEARANCE DATES BETWEEN 5/10/99 AND 4/30/04 THAT HAVE BEEN RECALLED
2013-2897	04/15/2013 05/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2898	04/15/2013 05/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Eric H. Weinberg The Law Firm of Eric H. Weinberg	NDA 22512
2013-2899	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K111543
2013-2900	04/15/2013 05/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 50706 - PHARMACOLOGY, TOXICOLOGY
2013-2901	04/15/2013 05/13/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	ROBRRT KING FDA NEWS	OAKDELL PHARMACY INC, SAN ANTONIO TX; HOME INTENSIVE CARE PHARMACY INC, SAN ANTONIO, TX; RECKITT BENCKISER INC, FORT WORTH, TX, ETC - 483S 3/1-31/13
2013-2902	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ROBERT KING FDANEWS	BRAINMASTER TECHNOLOGIES, BEDFORD, OH; NEOGEN CORP, LEXINGTON, KY; GEBAUER CO, CLEVELAND, OH - 483S 3/1-31/13
2013-2903	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	HYDRITE CHEMICALS, UNIVERSITY PARK, IL; MAR COR PURIFICATION CHICAGO, DOWNERS GROVE, IL; MEDIFIX INC, MORTON GROVE, IL - 483S 3/1-31/13
2013-2904	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	AMERICAN ANIBIOTICS INC, BALTIMORE, MD; AUTOMATED OPHTHALMICS, INC, COLUMBIA, MD; CALVARY SPINE LLC, TOWSON, MD - 483S 3/1-31/13
2013-2905	04/15/2013 05/13/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ROBERT KING FDANEWS	STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC - 483S 3/1-31/13
2013-2906	04/15/2013 05/13/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	PATRICIA L REGENYE Celgene Corporation	JONAHTAN BERNSTEIN,HEMOPHILIA TREATMENT CENTER OF LAS VEGAS, LAS VEGAS, NV - 483S 2/10/10 TO PRESENT

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2013-2907	04/15/2013 05/13/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	LEONARD VALENTINO,RUSH CHILDREN'S HOSPITAL, CHICAGO, IL - 483S 5/29/08, 6/30/08, 7/18/12, ETC
2013-2908	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANTON AMANN ROXANE LABORATORIES INC	DIPHENHYDRAMINE HCI CAPS ANDA 80-635 - RECS
2013-2909	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURITIS A THURSTON JR THURSTON LAW OFFICES	SEPTOCAINE NDA 20-9718/S009, NDA 20-971/S013 - CORR, STUDIES, RPTS, ETC
2013-2910	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	RONALD S GOLDSER ZIMMERMAN REED PLLP	ST JUDE MEDICAL - RIATA ICD LEADS P950022/S14; RITATA ST ICD LADS P950022/S24 RECS
2013-2911	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	SAM MEDICAL PRODUCTS, WILSONVILLE, OR - SAM JUNCTIONAL TOURNIQUET K123694
2013-2912	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAHLES, ANDRE	ORANGE BOOK - 2001-2010
2013-2913	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PETER S REICHERTZ SHEPPARD MULLILN RICHTER ET AL	LUITPOLD PHARMACEUTICALS INC - SPRIX, (KETOROLAC TROMETHAMINE) NASAL SPRAY NDA 22-382 5/1/10 TO PRESENT
2013-2914	04/15/2013 05/13/2013	FDA/OC/OES/DFOI/	Doe J	MEDICATION FOR NERVE DAMAGE - RECS
2013-2915	04/15/2013 05/13/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS J MCKENNA GAINEY MCKENNA & EGGLESTON	PEREGRINE PHARMACEUTICALS INC - BAVITUXIMAB PHASE II CLNCL TRIAL PROTOCOL
2013-2916	04/15/2013 05/13/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS J MCKENNA GAINEY MCKENNA & EGGLESTON	CLINICAL SUPPLIES MANAGEMENT INC - STANDARD OPERATING PROCEDURE (SOP), CLNCL PROTOCOLS, RPTS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-2917	04/15/2013 05/13/2013	FDA/OF/CFSAN/OCD/EOS/	NICOLE BROCHU SUN-SENTINEL	TEMPORARY HENNA TATTOOS, ORGANIC DYES IN PERMANENT TATTOOS - CMLPTS 1/1/11 TO 4/1/13
2013-2918	04/15/2013 05/13/2013	FDA/OF/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	SABIC INNOVATIVE PLASTICS - FCN 831
2013-2919	04/15/2013 05/13/2013	FDA/OC/OES/DFOI/	JOHN BONIFELD CNN	TRIAMCINOLONE INJ - DATE OF EXPOSURE, LOCATION OF FACILITY, TRANSPLANT PATIENTS, ETC
2013-2920	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MUNDINE, JEREMY	PAXIL - AERS
2013-2921	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MUNDINE, JEREMY	DEPAKOTE, SEROQUEL - AERS
2013-2922	04/15/2013 05/13/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	OLIVIA T LUK NIRO SCAVONE HALLER & NIRO	PREMIER LABS, AUSTIN, TX - GMP
2013-2923	04/15/2013 05/13/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	OLIVIA T LUK NIRO SCAVONE HALLER & NIRO	QUANTUM NUTRITIONAL LABS - GMP
2013-2924	04/15/2013 05/13/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	KROMENAKER, FRANK FRITZ	KIMBERLY-CLARK - WARNING LTRS 3/9/01, 6/4/08, 8/8/2012
2013-2925	04/15/2013 05/13/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	EDWARDS LIFESCIENCES LLC, IRVINE, CA - EIRS, 483S 2006 TO 2009
2013-2926	04/15/2013 05/13/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	JACKIE CALLAWAY ABC ACTION NEWS	ADORA BODY SCULPTING CLINIC, TAMPA, BRANDON, WESLEY CHAPEL. PALM HARBOR, FL - INSP PAST 12 MONTHS
2013-2927	04/15/2013 05/13/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	MARK C STANZIANO CHANFRAU & CHANFRAU	WHITNEY LABS, ORMOND BEACH, FL - RPTS
2013-2928	04/15/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH	CAERS 163796

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	05/13/2013		IOVATE HEALTH SCIENCES INTERNATIONAL INC	
2013-2929	04/15/2013 05/13/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	ROBERT KING FDA NEWS	AMGEN INC, LONGMONT, CO; NOVARAD CORP, AMERICAN FORK,UT; SORIN GROUP USA INC, ARVADA, CO, ETC - 483S 3/1-31/13
2013-2930	04/15/2013 05/13/2013	FDA/OGROP/ORACE-FO/DET- DO/DET-CB/	ROBERT KING FDANEWS	PORTAGE PHARMACY INC, PORTAGE, MI; DOW ARGOSCIENCES LLC, HARBOR BEACH, MI; BIOMEDIX INC, BLOOMINGTON, IN, ETC - 483S 3/1-31/13
2013-2931	04/15/2013 05/13/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	ROBERT KING FDANEWS	INSIGHT INSTRUMENTS INC, STUART, FL; AXIUM HEALTHCARE PHARMACY INC, LAKE MARY, FL; PINOOK- USA, ORLANDO, FL, ETC - 483S 3/1-31/13
2013-2932	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cagla KURFALI, Cagla	K032845, K013226, K101538
2013-2933	04/15/2013 05/13/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	CTP INDEPENDENT REVIEW OF AVAILABLE SCIENCE RELATED TO THE IMPACT OF MENTHOL CIGARETTES ON PUBLIC HEALTH (03/17/2011 - 04/12/2013)
2013-2934	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephanie Wright The Wright Family	EFFEXOR, EFFEXOR XR - AERS
2013-2935	04/15/2013 05/13/2013	CVM/OCD/ FDA/OF/CFSAN/OCD/EOS/	Dr Ryan M. Yamka Blue Buffalo Company	FIBER FOR HAIRBALL CLAIMS IN FELINE FOODS - WHITE PAPERS, REPORTS, ETC (04/01/2003 - 04/12/2013)
2013-2936	04/15/2013 05/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Benjamin Mettey Boston Biomedical Consultants, Inc.	APPLICATION OF ADVANCES IN NUCLEIC ACID AND PROTEIN BASED DETECTION METHODS TO MULTIPLEX DETECTION OF TRANSFUSION-TRANSMISSIBLE AGENTS AND BLOOD CELL ANTIGENS IN BLOOD DONATIONS - WORKSHOP TRANSCRIPTS
2013-2937	04/15/2013 05/13/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	Jeffrey Gordon Quinn Emanuel Urquhart & Sullivan, LLP	07/11/86 LETTER FROM JW SWANSON TO PHILLIPPE DOUILLETT, DOCKET NUMBER 83P-0404; 07/31/73 MEMO FROM DR ALFRED WEISSLER RE ASBESTOS IN TALC 2
2013-2938	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	CIPLA LTD, DHAR, INDIA; CHEMAGIS LTD, BEER SHEVA, ISRAEL, AMGEN TECHNOLOGY IRELAND, DUBLIN IRELAND, ETC - 483S 3/1-31/13
2013-2939	04/15/2013 05/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIEBSCHUTZ Isabelle LABORATOIRES PLASTO SANTE	LABORATOIRES FOURNIER, FRANCE - INSPECTION REPORT 5/19/98

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-2940	04/15/2013 05/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	USCOM LTD, SYDNEY, AUSTRALIA; ALPINION MEDICAL SYSTEMS, SEOUL, SOUTH KOREA; LIGHTMED CORP, SHULIN DISTRICT, NEW TAIPEI CITY, TAIWAN, ETC - 483S 3/1-31/13
2013-2941	04/15/2013 05/13/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ROBERT KING FDANEWS	MERIDIAN MEDICAL TECHNOLOGIES, BRENTWOOD, MO; CONTINENTAL MANUFACTURING CHEMIST INC, MADRID, IA; MEGA SUN INC, ST LOUIS, MO, ETC - 483S 3/1-31/13
2013-2942	04/15/2013 05/13/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ROBERT KING FDANEWS	CA BOTANA INTERNATIONAL INC, SAN DIEGO, CA; NEXGEN PHARMA INC, IRVINE, CA; PACIRA PHARMACEUTICALS INC, SAN DIEGO, CA, ETC - 483S 3/1-31/13
2013-2943	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	STEARNS PACKAGING CORP, MADISON, WI; PRISM CLINICAL IMAGING INC, ELM GROVE, WI; ESCALON MEDICAL CORP, NEW BERLIN, WI, ETC - 483S 3/1-31/13
2013-2944	04/15/2013 05/13/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ROBERT KING FDANEWS	BIOGEN IDEC INC, CAMBRIDGE, MA; REMOTE TECHNOLOGIES INC, GREENWICH, CT; HEMEDEX INC, CAMBRIDGE, MA, ETC - 483S 3/1-31/13
2013-2945	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDANEWS	DIMENSIONAL MERCHANDISING INC, WHARTON, NJ; SIEGFRIED USA LLC, MIDDLESEX, NJ; ULTRARAD CORP, WEST BERLIN, NJ, ETC - 483S 3/1-31/13
2013-2946	04/15/2013 05/13/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	SHOWA BEST GLOVE INC, FAYETTE, AL; TINGLE X-RAY PRODUCTS INC, COTTONSALE, AL; EXXON MOBIL CHEMICAL CO, BATON ROUGE, LA, ETC - 483S 3/1-31/13
2013-2947	04/15/2013 05/13/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDANEWS	INVAGEN PHARMACEUTICALS INC, HAUPPAUGE, NY; IMMCO DIAGNOSTICS INC, BUFFALO, NY; PREMIER HEART LLC, PORT WASHINGTON, NY, ETC - 483S 3/1-31/13
2013-2948	04/15/2013 05/13/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ROBERT KING FDANEWS	SPRAY-TEK INC, BETHLEHEM, PA - 483S 3/1-31/13
2013-2949	04/15/2013 05/13/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBERT KING FDANEWS	FVS HOLDINGS INC (GREEN VALLEY DRUGS), HENDERSON, NV; NEUROPACE INC, MOUNTAIN VIEW, CA; SENTRELHEART INC, REDWOOD CITY, CA, ETC - 483S 3/1-31/13
2013-2950	04/15/2013 05/13/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	CERAMCO MANUFACTURING BV, LAS PIERDAS, PR; NEOLPHARMA INC, CAGUAS, PR; AGROPHARMA LABORATORIES INC, SALINAS, PR - 483S 3/1-31/13
2013-2951	04/15/2013 05/13/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDANEWS	MIRADOR BIOMEDICAL INC, SEATTLE, WA; MICROSURGICAL TECHNOLOGY INC, REDMOND, WA; INOVISE MEDICAL INC, BEAVERTON, OR, ETC - 483S 3/1-31/13
2013-2952	04/15/2013	ORA/	ROBERT KING	BHARAT ENTERPRISES, DELHI, INDIA - 483S 3/1-31/13

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2013-2953	04/15/2013 05/13/2013	FDA/OC/OES/DFOI/	ADAM BUTSCHEK CAUSE OF ACTION	DISCRETIONARY, NON-FORMULA GRANTS, GRANT RECEIPIENTS, ETC - RECS
2013-2954	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tang Peng ChemWerth, Inc.	MICROTROL STERILIZATION SERVICES PVT LTD, KARNATAKA, INDIA - EIR 10/25/12
2013-2955	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A&S Pharmaceutical Corp A&S Pharmaceutical Corp	NOVACYL LIMITED, THAILAND - EIR, 483 (01/01/2012 - 04/01/2013)
2013-2956	04/16/2013 05/14/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Aaron D Schneider Dole Fresh Vegetables, Inc.	DOLE FRESH VEGETABLES, INC, BESSEMER CITY, NC - DIARY NOTES (06/29/2012 - 07/03/2012)
2013-2957	04/16/2013 05/14/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Aaron Schneider Dole Fresh Vegetables, Inc.	DOLE FRESH VEGETABLES, INC, BESSEMER CITY, NC - DIARY NOTES (03/18/2013 - 03/21/2013)
2013-2958	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marlena S Fejzo UCLA	STUDY ON DICLECTIN/DICLEGIS EFFECTIVENESS, SAFETY, SIDE EFFECTS ETC
2013-2959	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz MANDELL HORWITZ CONSULTANTS LLC	K910944
2013-2960	04/16/2013 05/14/2013	FDA/OGROP/ORA/ORO/DIOP/ ORA/ORO/DFS/ ORA/ORO/DFS/	Kari Umholtz Umholtz, Kari A	SEAFOOD IMPORTED FROM CHINA - ILLEGAL NITROFURANS, MALACHITE RESIDUE, MELAMINE, ETC
2013-2961	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gopal Reddy Palvatla EASTERN MICHIGAN UNIVERSITY	FENTORA, FENTANYL CITRATE - MEDWATCH RPTS (01/01/2003 - 12/31/2012)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-2962	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K082018
2013-2963	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dheeresh Pathak Self	WOCKHARDT, INDIA - 483 (01/01/2013 - 04/14/2013)
2013-2964	04/16/2013 05/14/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Robert Blaskiewicz Skeptics for the Protection of Cancer Patients	BURZYNSKI CLINICAL - RESPONSES TO 483 (09/14/2012 - 05/14/2013)
2013-2965	04/16/2013 05/14/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	Matt Jordan STRYKER MEDICAL	HILL-ROM COMPANY - 01/11/13 RESPONSE TO 483 AND RELATED RECS
2013-2966	04/16/2013 05/14/2013	FDA/OC/OES/DFOI/	Donald Segal ALSTON & BIRD LLP	FOIA REQUESTS FOR FAP 2A4796 (01/01/2013 - 04/15/2013)
2013-2967	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	UNIMED SURGICAL - UNITED COATED LAPAROSCOPIC ARTHROSCOPY SUCTION IRRIGATION ELECTRODE K970066
2013-2968	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	UNIMED SURGICAL PRODUCTS INC - UNIMED COATED NEEDLE ELECTRODE, COATED BLADE ELECTRODE, COATED BALL ELECTRODE K962935
2013-2969	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAONNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN ELECTRODE K913473
2013-2970	04/16/2013 05/14/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN LAPAROSCOPIC ELECTRODE K913281
2013-2971	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	AMERICAN MEDICAL PRODUCTS INC - EZ CLEAN K862221
2013-2972	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN ELECTROSURGICAL ELECTRODE K081791
2013-2973	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOANNE CONDE XODUS MEDICAL	MEGADYNE MEDICAL PRODUCTS INC - EZ CLEAN ELECTROSURGICAL ELECTRODE K081791
2013-2974	04/16/2013 05/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	JOANNE CONDE XODUS MEDICAL	UNIMED SURGICAL PRODUCTS INC, LARGO, FL - AUDITS 1/10 TO 1/12

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		FDA/OC/OES/DFOI/		
2013-2975	04/16/2013 05/14/2013	FDA/OF/CFSAN/OCD/EOS/	A. YOUNG USA TODAY	REUMOFAM; WOW - CAERS 1/13 TO 4/13
2013-2976	04/16/2013 05/14/2013	FDA/OF/CFSAN/OCD/EOS/	ELBEK, GAIL	SOY INFANT FORMULA - CAERS
2013-2977	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STEVEN NAPOLITANO SKADDEN ARPS SLATE MEAGHER & FLOM	PROPOXYPHENE HYDROCHLORIDE ANDA 040-908 APRVL
2013-2978	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	TARO PHARMA - TOPICORT NDA 204-141 SBA
2013-2979	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LISA CHIARINI HUGHES HUBBARD & REED	PROLENSA NDA 20-3168
2013-2980	04/16/2013 05/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL D. SHUMSKY KIRKLAND & ELLIS LLP	TECFIDERA NDA 204-063
2013-2981	04/16/2013 05/14/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	STEPHEN J. CARR AKERMAN SENTERFITT ATTYS	ELECTROSTIM MEDICAL SERVICES INC - EIR
2013-2982	04/17/2013 05/15/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OFO/OFM/BTAMS / FDA/OMPT/CTP/OD/ FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	TOBACCO MANUFACTURER AND IMPORTER USER FEES ASSESSED BY FDA CTP - ALL RECS AND CORR (06/22/2009 - 04/15/2013)
2013-2983	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dr Mike Williams Dr. Mike Williams	K061688, K092942, K090503
2013-2984	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies Inc.	K993956
2013-2985	04/17/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	William Hite	LONZA BIOLOGICS, PORTSMOUTH, NH - DRUG QUALITY ASSURANCE REVIEW, 483

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2013-2986	04/17/2013 05/15/2013	FDA/OMPT/CTP/OD/	Allison O'Donnell Campaign for Tobacco Free Kids	MTG BETWEEN TOBACCO MANUFACTURERS AND FDA 5/2/12 - SUBMISSIONS, DISCUSSIONS, ATTENDENCE, ETC
2013-2987	04/17/2013 05/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Keli Renner Renner, Keli C	ZOSTAVAX - VAERS
2013-2988	04/17/2013 05/15/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG (04/08/2013 - 04/12/2013)
2013-2989	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Zupke Michael Zupke	BUPROPION - BIOEQUIVALENCE
2013-2990	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K102924
2013-2991	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K092561
2013-2992	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K101996
2013-2993	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K071082
2013-2994	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K110599
2013-2995	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Atul Khare Akorn, Inc.	ANDA 078711
2013-2996	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K963043
2013-2997	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document	K100866

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			Retrieval	
2013-2998	04/17/2013 05/15/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483, EIR, INSPECTIONS (03/20/2013 - 04/15/2013)
2013-2999	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams FOI Services, Inc.	K122698
2013-3000	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Matthew Miller MEYERSON & O'NEILL ATTY	INFUSE BONE GRAFT IN DENTAL AND SINUS AUGMENTATION PROCEDURES - SAFETY AND EFFICACY
2013-3001	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Howard Brittain Howard Brittain	NITROFURATOIN - AERS (01/01/2008 - 01/01/2013)
2013-3002	04/17/2013 05/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MEADE, DORIS.	FINEMOST CORP (QUALIHERB), CERRITOS, CA - 483 9/12-21/12
2013-3003	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY C CHAMBERS RONALD R BENJAMIN LAW OFC	INDIVIDUAL RECS
2013-3004	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	NORMAN W PAULI JR PAULI LAW FIRM	INDIVIDUAL RECS
2013-3005	04/17/2013 05/15/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JOLENE LAKEY Glanbia Nutritionals (NA)	GLANBIA NUTRITIONALS, SPRINGFIELD, MO - EIR 8/28/12
2013-3006	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	TOM HAUERTER ORTHO DEVELOPMENT CORP	K050210
2013-3007	04/17/2013 05/15/2013	OC/OL/	RORY CAMPBELL DEMOCRATIC SENATORIAL CAMPAIGN COMMITTEE	CONGRESSMAN STEVE KING - CORR 6/1/11 TO 4/11/13
2013-3008	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CROSBY T-50417, COURTNEY	PRADAXA - DEAR DOCTOR LTRS, PRESCRIBING INFO
2013-3009	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARAH SCHARF ROSS MEDICAL	K072558, K071995
2013-3010	04/17/2013	FDA/OMPT/CDER/GRP/DIDP/	NATHAN JORGENSEN, Ph.D.	AMPYRA - EFFICACY

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	05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stifel Nicolaus & Co	
2013-3011	04/17/2013 05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	LILLY ELIZABETH DWARKA EQUIPMENTS PVT LTD	MYCO MEDICAL - GLASS VAN GLASS SYRINGE K963364; PROCEDURE PRODUCTS INC - GLASS SYRINGE, DRUG LUER K820384, ETC
2013-3012	04/17/2013 05/15/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF223200830014I - TASK ORDERS, WINNING PROPOSAL, CONTRACT, ETC
2013-3013	04/17/2013 05/15/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	ION BEAM APPLICATIONS, UINIONVILLE, NY; RICHMOND, VA; SOMERSET, NJ, ETC - 483S
2013-3014	04/17/2013 05/15/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	MICHAEL NAZERIAS PETNET SOLUTIONS INC	ION BEAM APPLICATIONS, MACON, GA; MOBILE, AL; CHARLESTON, SC, ETC - 483S
2013-3015	04/17/2013 05/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERZ PHARMS - XEOMIN (INCOBOTULINUMTOXIN A) BLA 125360/007 APRVL LTR
2013-3016	04/17/2013 05/15/2013	ORA/ORM/ ORA/ORM/	WALTER E CHALKLEY THOMSON REUTERS	LIST OF INSPS 1996
2013-3017	04/17/2013	ORA/	TOM CORWIN	CLINICAL SPECIALTIES COMPOUNDING PHARMACY,

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	05/15/2013	ORA/	AUGUSTA CHRONICLE	AUGUSTA, GA; MARTINEZ, GA - INSPS 3/13
2013-3018	04/17/2013	ORA/OE/	ALISON YOUNG	DIETARY SUPPLEMENT FIRMS - 483S 1/08 TO PRESENT
	05/15/2013	ORA/OE/	USA TODAY	
2013-3019	04/17/2013	FDA/OMPT/CDER/GRP/DIDP/	LEIGH SANDERS	MATTEK - EPIDERM, EPIOCULAR ANIMAL TESTING RECS
	05/15/2013	FDA/OMPT/CDER/GRP/DIDP/	CENTER FOR RESPONSIBLE	
		FDA/OMPT/CDER/GRP/DIDP/	SCIENCE	
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3020	04/18/2013	FDA/OMPT/CDER/GRP/DIDP/	Birgitta Gassner	FORMULATION DEVELOPMENT OF REMODULIN,
	05/16/2013	FDA/OMPT/CDER/GRP/DIDP/	REDL Life Science Patent	JUSTIFICATION FOR FINAL COMPOSITION OF SOLUTION
		FDA/OMPT/CDER/GRP/DIDP/	Attorneys	FOR INFUSION
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3021	04/18/2013	FDA/OGROP/ORA/CE-FO/DET-	Jim McNair	ALIGN TECHNOLOGY, BIOMET INC, DUPUY ETC - 483
	05/16/2013	DO/DET-CB/	none	(07/01/2012 - 04/15/2013)
		FDA/OGROP/ORA/PA-FO/SAN-		
		DO/SAN-CB/		
		FDA/OGROP/ORA/SE-FO/FLA-		
		DO/FLA-CB/		
		FDA/OGROP/ORA/SE-FO/NOL-		
		DO/NOL-CB/		
		FDA/OC/OES/DFOI/		
2013-3022	04/18/2013	FDA/OMPT/CTP/OD/	Desmond Jenson	TOBACCO ESTABLISHMENT REGISTRATION AND TOBACCO
	05/16/2013		Tobacco Control Legal Consortium	PRODUCT LISTING - ALL RECS AND CORR (06/22/2009 -
				04/16/2013)
2013-3023	04/18/2013	FDA/OC/OES/DDM/	Jason Leckerman; Marcel Pratt	FDA'S CONSIDERATION AND ANALYSIS OF VALEANT
	05/16/2013	FDA/OMPT/CDER/GRP/DIDP/	BALLARD SPAHR LLP	PHARMACEUTICALS INTERNATIONAL INC'S CITIZEN
		FDA/OMPT/CDER/GRP/DIDP/		PETITION
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3024	04/18/2013	FDA/OGROP/ORA/CE-FO/CHI-	Melanie Jackson	PQ CORPORATION, UTICA, IL - MOST RECENT 483 AND
	05/16/2013	DO/CHI-CB/	Fresenius Kabi USA, LLC	RESPONSE
2013-3025	04/18/2013	FDA/OMPT/CDER/GRP/DIDP/	Trupti Shah Takeda	TAKEDA AFFYMAX - LISTING OF 156 CASES
	05/16/2013	FDA/OMPT/CDER/GRP/DIDP/	TAKEDA PHARMACEUTICALS NA	
		FDA/OMPT/CDER/GRP/DIDP/	INC	
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3026	04/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon	K091423

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	05/16/2013		LexisNexis CourtLink Document Retrieval	
2013-3027	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K041114
2013-3028	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K021346
2013-3029	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K121308
2013-3030	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K092406
2013-3031	04/18/2013 05/16/2013	FDA/OF/CFSAN/OCD/EOS/	Dr. Byron Shock Scientific Ecological Services, Inc.	OUTBREAK DATABASE DATA
2013-3032	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Traci Lillyroot Mortara Instrument, Inc	MEDWATCH FORM DEVICE EVENT KEY 2168692
2013-3033	04/18/2013 05/16/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ ORA/ ORA/	Mallory Shiflett Shiflett, Mallory E	CENTREVILLE VA WAREHOUSE MANUFACTURING ZI XIU TANG BEE POLLEN - INVESTIGATION RECS (10/01/2012 - 04/16/2013)
2013-3034	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mihir Zaveri UC Berkeley Graduate School of Journalism	RECALL Z-1896-2009, Z-3056-2011 - HHE; HRA FOR RESOLUTION CLIP MODEL M00522600, M00522601, M00522602 ETC
2013-3035	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	K081044
2013-3036	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bruce McKeeman SUMMIT TO SEA LLC	INVESTIGATION OF FRAUDULENT EMAIL RE MEDWATCH REPORT (07/16/2012 - 04/16/2013)
2013-3037	04/18/2013	FDA/OGROP/ORACE-FO/DET-	Eileen Barbary	WILLIAM BEAUMONT HOSPITAL RESEARCH DEPARTMENT,

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	05/16/2013	DO/DET-CB/	Berbary, Eileen	KELLY SAWYER, SIMON DIXON - 483, WARNING LETTER (04/01/2000 - 04/16/2013)
2013-3038	04/18/2013 05/16/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MITTAL SUTARIA Sutaria, Mittal	LIST OF NDA OR BLA SUBMITTED FOR NEW MOLECULAR ENTITIES SINCE JANUARY 2012; LIST OF NDA OR BLA CURRENTLY UNDER REVIEW; LIST OF NDA OR BLA TO BE DISCUSSED AT UPCOMING ADVISORY MEETINGS
2013-3039	04/18/2013 05/16/2013	FDA/OF/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC	FCN 1025
2013-3040	04/18/2013 05/16/2013	FDA/OF/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC.	FCN 1035
2013-3041	04/18/2013 05/16/2013	FDA/OF/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC	FCN 1094
2013-3042	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Saket Bhatt COVIDIEN	K934193
2013-3043	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Goodenough Integrated Technologies Ltd	K110962
2013-3044	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K060537
2013-3045	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sara Borrelli Jackson Walker L.L.P.	K922457
2013-3046	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K012031
2013-3047	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K052547
2013-3048	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112161
2013-3049	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K111262
2013-3050	04/18/2013 05/16/2013	ORA/ ORA/	Elizabeth Engebretson Engebretson, Elizabeth	PHARMEDIUM - 483 (02/01/2013 - 04/17/2013)
2013-3051	04/18/2013 05/16/2013	FDA/OC/OES/DDM/	LAURA S SUTTELL PHILLIPS LYTLE ET AL	DKT 1975-N-0301

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2013-3052	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	KENDALL CO, MANSFEILD, MA - EXCILON AMD AMTIMICROBIAL SPONGE K011941
2013-3053	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE YUTKIN STEPHANIE YUTKIN COUNSELOR AT LAW	BIOENTERICS CORP - LAP-BAND SYS POST-MARKET US STUDY PMA APRVL APPLICATION, SUPPL TO PMA 5/25,31/01
2013-3054	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	SARA BEARDSLEY SIDLEY AUSTIN LLP	NEMOTO KYORINDO CO LTD - SONIC SHOT GX CONTRAST DELIVERY SYS K091734
2013-3055	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	HAMILTON PHD, LEROY L	CDRH OMBUDSMAN - POSITION DESCRIPTION
2013-3056	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RICHARD NORTON INNOVATIVE PHARMACEUTICALS	NDA 50-703 - SBA
2013-3057	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORO/ORO/DIOP/	MANUEL A MOLINA FREEHILL HOGAN & MAHARR LLP	SANDHYA MARINES LTD, INDIA - FROZEN SHRIMP EIRS, WARNING LTRS, UNTITLED LTRS
2013-3058	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	FRANK DONATH SOCRATEC R&D	SOCRATEC R&D,ERFURT, GERMANY - EIRS 8/27-31/12
2013-3059	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUZIE KESCHAMRUS AVANIR PHARMACEUTICALS INC	NUJEDXTA (DEXTROMETHORPHAN HYDROBROMIDE) NDA 21-879 - AERS
2013-3060	04/18/2013 05/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/	JANET Y SANTANA FEDERAL PUBLIC DEFENDER TENNESSEE	PENTOBARBITAL (DEA CODE 2270) & NONCONTROLLED ACTIVE INGREDIENT (DEA CODE 2271) - IMPORT, TRANSPORT, NOTICE OF ACTION, ETC

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		ORA/ FDA/OGROP/ORA/ORO/DIOP/		
2013-3061	04/18/2013 05/16/2013	CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	TILMICOSIN ANADA 200-509 - LBLG PKG
2013-3062	04/18/2013 05/16/2013	FDA/OC/OES/	LIPPERT #B74054, DON	ILLINOIS CORRECTIONAL INDUSTRIES- FOOD & DAIRY PROCESSING PLANTS LAST 5 YRS
2013-3063	04/18/2013 05/16/2013	FDA/OMPT/OSMP/OOPD/	CHRISTOPHER P ADAMAS ANDARIX PHARMACEUTICALS INC	IMMUNOMEDICS INC, MORRIS PLAINS, NJ - CEA-CIDE (MN14 MONOCLONAL ANTIBODY TO CARCINOEMBRYONIC ANTIGEN) DRUG APPLICATION 9/18/98
2013-3064	04/18/2013 05/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHEN, JOHN	FINEMOST CORP (QUALIHERB), CERRITOS, CA - WARNING LTR 32-1 483, VIOLATIONS, RESP TO 483, ETC
2013-3065	04/18/2013 05/16/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	KIRSTEN CULTRARA DIETRICH LAW FIRM PC	FARM RICH FOODS OR RICH PRODUCTS - RECALL INVESTIGATION
2013-3066	04/18/2013 05/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHEN, JOHN	GM MANUFACTURING INC, GARDENA, CA - WARNING LTR 2912 483, VIOLATION, RESP TO WARNING LTR, ETC 7/23/12
2013-3067	04/18/2013 05/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	JOHN A BERANBAUM BERANBAUM MENKEN LLP	NEW YOR DOWNTOWN HOSPITAL - LTR 8/12
2013-3068	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	SINGULAR MONTELUKAST TABS - AERS
2013-3069	04/18/2013 05/16/2013	FDA/OO/OFBA/OAGS/	ROSE SANTOS FOIA GROUP INC	HHSF22301110044G
2013-3070	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K963046
2013-3071	04/18/2013 05/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Goodenough Integrated Technologies Ltd	K093186
2013-3072	04/18/2013 05/16/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	BOTOX - RECS 1/11 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/		
2013-3073	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEITH MCWHA MCCARTER & ENGLISH LLP	HOSPIRA - DAPTOMYCIN NDA 203-797 RECS
2013-3074	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MYLAN PHARMS INC - ACYCLOVIR ANDA 202-459 SBA
2013-3075	04/19/2013 06/11/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/	JOEL KURTZBERG CAHILL GORDON & REINDEL	FDA EXPERIMENTAL STUDY OF GRAPHIC CIGARETTE WARNING LABELS - RECS
2013-3076	04/19/2013 05/17/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	AVDEEF, STEPHEN M	CDC, SAM'S CLUB, WALMART, ETC - BURKHOLDERIA CAPACIA RECALL, CORR, RPTS, ETC 2006
2013-3077	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	CDER FOIA REQUEST LOG 1/13 TO PRESENT
2013-3078	04/19/2013 07/31/2013	FDA/OF/CFSAN/OCD/EOS/	KRISTI O CMEDLEY PHD Center for Regulatory Services, Inc.	COGNIS DEUTSCHLAND GMBH & CO KG - FCN 618
2013-3079	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	XIMENA VAN DEN ENDEN ricoh orthodontic appliances inc	K113516
2013-3080	04/19/2013 05/17/2013	FDA/OF/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	VITAMIN K-1 (PHYRONADIONE) - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3081	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber, PhD The Dartmouth Institute Ctr for Med	ESIDRIX NDA 11793; HYDRODIURIL NDA 11835; ORETIC NDA 11971 ETC - APPROVAL RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	and Media	
2013-3082	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K963044
2013-3083	04/19/2013 05/17/2013	FDA/OF/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	SODIUM MOLYBDATE DEHYDRATE - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3084	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eileen Flowers Jefferies, LLC	ICLUSIG - AERS
2013-3085	04/19/2013 05/17/2013	FDA/OF/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	DISODIUM SELENITE - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3086	04/19/2013 05/17/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	SUBSTANTIAL EQUIVALENT ORDER LETTERS AND NON-SUBSTANTIAL ORDER LETTERS ISSUED BY CTP 06/22/2009 - 04/17/2013
2013-3087	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Please help me Alliance institute	QBD IMPLEMENTED PDR FOR GLIMEPIRIDE
2013-3088	04/19/2013 05/17/2013	FDA/OF/CFSAN/OCD/EOS/	ARLENE MORALES BURDOCK GROUP	CHROMIUM CHLORIDE - REGULATORY STATUS, CONSUMPTION, SAFETY RECS, ETC
2013-3089	04/19/2013 05/17/2013	FDA/OC/OES/ FDA/OC/OPP/OP/ FDA/OMPT/CDRH/OCER/DFOI/	Peter Spaulding Peter Spaulding	CORR BETWEEN FDA AND DR ALVARO PASCUAL-LEONE RE CRANIAL ELECTROTHERAPY STIMULATION DEVICES NEUROLOGICAL DEVICES PANEL 08/01/2011 TO PRESENT
2013-3090	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Reichard Shamrock Medical Solutions Group, LLC	SHAMROCK MEDICAL SOLUTIONS GROUP, LLC - UNREDACTED HEALTH HAZARD EVALUATIONS
2013-3091	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K913881
2013-3092	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diana L. Martone CORIN USA	K994152
2013-3093	04/19/2013 05/30/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Edward K. Phillips International Marine Products Los	IMP FOODS, SAN MATEO, CA - EIR, 483, IMPORT ALERT (11/01/2010 - 04/17/2013)

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			Angeles	
2013-3094	04/19/2013 05/17/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Ed Skepnek Valnet Inc.	MEDIVATORS, CONROE, TX - EIR (11/15/2012 - 01/15/2013)
2013-3095	04/19/2013 05/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natalie Corrick AstraZeneca Pty Ltd	CAMBREX KARLSOGA - EIR (01/01/2011 - 01/31/2011)
2013-3096	04/19/2013 05/17/2013	ORA/ ORA/	Doe J	INDIVIDUAL RECS
2013-3097	04/19/2013 05/17/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	Jeffrey Gordon Quinn Emanuel Urquhart & Sullivan, LLP	7/11/86 LETTER FROM JW SWANSON TO PHILLIPPE DOUILLET, 83P-0404; 7/31/73 MEMO FROM ALFRED WEISSLER RE TALC (CERTIFIED)
2013-3098	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Francois Binette, Ph.D. BioTime	K070496
2013-3099	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K955556
2013-3100	04/19/2013 05/17/2013	ORA/OCI/ ORA/OCI/	Patricia Perez Perez, Patricia L	OCI 2006-MIF-705-0298 - CERTIFIED RECS
2013-3101	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K801036
2013-3102	04/19/2013 05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K934085
2013-3103	04/19/2013 05/17/2013	FDA/OF/CFSAN/OCD/EOS/	Jim Faller Valley Chemical Solutions, Inc.	FAP 2A4736, FAP 6A4767
2013-3104	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/25-29/13
2013-3105	04/19/2013 05/17/2013	FDA/OGROP/ORASW-FO/NWE-DO/NWE-CB/	Jonathan Harrington Olympus Biotech Corporation	STERIS ISOMEDIX SERVICES, NORTHBOROUGH, MA 0- EIR (10/17/2011 - 10/19/2011)
2013-3106	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 3/25-29/13
2013-3107	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/25-29/13
2013-3108	04/19/2013	FDA/OC/OES/DFOI/	DEBI COHEN	DAILY LOG 3/25-29/13

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	05/17/2013		WOLTERS KLUWER LAW & BUSINESS	
2013-3109	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/18-22/13
2013-3110	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 3/18-22/13
2013-3111	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services, Inc.	DAILY LOG 3/25-29/13
2013-3112	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	WILLIAM A. OLSON, Ph.D. Center for Regulatory Services, Inc.	DAILY LOG 3/18-22/13
2013-3113	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 3/18-22/13
2013-3114	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 3/25-29/13
2013-3115	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/18-22/13
2013-3116	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/18-22/13
2013-3117	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 3/25-29/13
2013-3118	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/25-29/13
2013-3119	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/18-22/13
2013-3120	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/18-22/13
2013-3121	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 3/25-29/13
2013-3122	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 3/18-22/13
2013-3123	04/19/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR	DAILY LOG 3/25-29/13

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	05/17/2013		JH BARR & ASSOCIATES LLC	
2013-3124	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 3/25-29/13
2013-3125	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 3/18-22/13
2013-3126	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 3/18-22/13
2013-3127	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	WEEKLY CLOSED LOG 3/25-29/13
2013-3128	04/19/2013 05/17/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 3/18-22/13
2013-3129	04/22/2013 05/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tony Fiorino Greywall Asset Management	EXPAREL - STATISTICAL REVIEW, UNREDACTED MEDICAL REVIEW
2013-3130	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nathan A. Beaver FOLEY & LARDNER LLP	K955557
2013-3131	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	ALL ORDERS ISSUED PURSUANT TO SECTION 911 OF THE FDCA APPROVING OR DENYING APPLICATION TO MARKET A TOBACCO PRODUCT AS A MODIFIED RISK TOBACCO PRODUCT (06/22/09 TO PRESENT)
2013-3132	04/22/2013 05/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	TZ-3 APPROVAL PACKAGE
2013-3133	04/22/2013 05/20/2013	FDA/OGROP/ORAC/CE-FO/CIN-DO/CIN-CB/	Sarah Tribble THE PLAIN DEALER	BEN VENUE - WARNING LETTERS, INSPECTION REPORTS, CONSENT DECREES ETC SINCE 01/01/13
2013-3134	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	SUBSTANTIAL EQUIVALENT ORDERS ISSUED UNDER SECTION 910(a)(2)(A) OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT, IDENTITY OF PRODUCT, IDENTITY OF MANUFACTURER 03/01/13 TO 3/31/13
2013-3135	04/22/2013 05/20/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/	Robert D. Sullivan, Jr. Wilson, Elser, Moskowitz, Edelman & Dicker LLP	RECS RE THREE LOTS OF PRESERVATIVE-FREE METHYLPREDNISONE ACETATE MANUFACTURED BY NECC ASSOCIATED WITH THE MULTI-STATE OUTBREAK OF FUNGAL MENINGITIS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/		
2013-3136	04/22/2013 05/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	NDA 019355 - APPROVAL RECS
2013-3137	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	ADVANCED BIONICS HIFOCUS MID-SCALA ELECTRODE - APPLICATION SUBMISSION DATE
2013-3138	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	MODIFIED RISK TOBACCO APPLICATIONS JUNE 22, 2009 TO PRESENT
2013-3139	04/22/2013 05/20/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Rachel Johnson FOI Services, Inc.	ANIMAS, WEST CHESTER, PA - 483 (07/18/2011 - 08/10/2011)
2013-3140	04/22/2013 05/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	07/20/1984LETTER FROM DR PAUL LEBER TO SPONSORS OF NEUROLEPTIC DRUGS RE TARDIVE DYSKINESIA WARNINGS, SUBSEQUENT CORR
2013-3141	04/22/2013 05/20/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Garrison Wells THE GAZETTE OF THE DEMONCRATIC SOCIALIST REPUBLIC OF SRI LANKA	MEDWATCH MESSAGES SENT TO FDA RE WARFARIN AND CONCERNS THAT DOSAGES HARMING PATIENTS IN COLORADO SPRINGS
2013-3142	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K934985
2013-3143	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K992485
2013-3144	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll MEDOVATIONS INC	K103707
2013-3145	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Boll Medovations Inc.	K020135

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2013-3146	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elaine Duncan Paladin Medical, Inc.	K111920
2013-3147	04/22/2013 05/20/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	SAMUEL GOLDBERGER BLUE BEVERAGE	BERNER FOOD AND BEVERAGE, DAKOTA, ILLINOIS - 483
2013-3148	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	I-STAT CELITE ACT CARTIDGE - K992571; I-STAT KAOLIN ACT CARTIDE - K023582
2013-3149	04/22/2013 05/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	NATHAN A BEAVER FOLEY & LARDNER LLP	LIST OF CURRENT MEDICAL DVCS - 510KS, PMAS 2013
2013-3150	04/22/2013 05/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	SAGENT STRIDES - BACITRACIN INJ; FERA PHARMS - NEOMYCIN, POLYMYXIN B SULFATES anda 90-211 & BACITRACIN ZINC OINTMENT ANDA 60-764 - AERS
2013-3151	04/22/2013 05/20/2013	FDA/OGROP/ORACE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	NYPRO, NC - EIR, 483, WARNING LETTER ETC (01/01/2009 TO PRESENT)
2013-3152	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	COMMONWEALTH BRANDS - FOLLOW UP RECS (07/20/2010 - 04/19/2013)
2013-3153	04/22/2013 05/20/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	PHILIP MORRIS USA - FOLLOW UP TO 6/17/10 LETTER RE MARKETING MARLBORO LIGHT
2013-3154	04/22/2013 05/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LAUREN MILLER ARNOLD AND PORTER	PERJETA (VISMODEGIB) BLA 12-5409 - APRVL LTR (CETIFIED)
2013-3155	04/22/2013 05/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-3156	04/22/2013 05/20/2013	FDA/OF/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	ENZYME BIO SYSTEMS LTD - FAP 9A4175
2013-3157	04/22/2013 05/20/2013	FDA/OF/CFSAN/OCD/EOS/	DONNAMARIA R JONES UNIFORMED SERVICES UNIVERSITY OF HEALTH SCIENCES	CAFFEINE & ENERGY DRINKS - CAERS 1/12 TO 12 /12
2013-3158	04/22/2013	ORA/ORM/	WALTER E CHALKLEY	LIST OF INSP - COMPANY, LOCATION, INSPECTORS 1999

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	05/20/2013	ORA/ORM/	THOMSON REUTERS	
2013-3159	04/22/2013	ORA/		RONALD CHESMORE - JOHN M HAMMOND, C EDWARD WEBB, MAUDE BABINGTON, ETC LTR 7/29/92
	05/20/2013	ORA/	KYRIALKDIS, JOANNA	
2013-3160	04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE	CURVEBEAM LLC - PEDCAT K113548
	05/20/2013		CARESTREAM HEALTH INC	
2013-3161	04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE	PLANMED OY - PLANMED VERITY K121418
	05/20/2013		CARESTREAM HEALTH INC	
2013-3162	04/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHERRI RUARK	ZOLL MEDICAL CORP - AED PLUS MDRS 1/02 TO 12/02
	05/20/2013		BRUER WOODDELL & HARRELL	
2013-3163	04/22/2013	FDA/OMPT/CDER/GRP/DIDP/	JANET Y SANTANA	IMPORTATION OF PHENOBARBITAL DEA SCHEDULE IV
	05/20/2013	FDA/OMPT/CDER/GRP/DIDP/	FEDERAL PUBLIC DEFENDER	CONTROLLED SUSTANCE DEA CODE #2285 - IMPORT,
		FDA/OMPT/CDER/GRP/DIDP/	TENNESSEE	ENTRY NOTICE OF FDA ACTION, ETC
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OGROP/ORA/ORO/DIOP/		
2013-3164	04/22/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE	BOXES PREPAERATIONS FORHAIR SHAMPOO & HAIR
	05/20/2013		ZETETIC	CONDITIONER IN 8 PALLETS ENTRY NUMBER EHP-0076994-4 - PHOTOGRAPHS, OASIS SCREEN SHOTS
2013-3165	04/22/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE	PALLETS CONTAINING SHAMPOO CONDITIONERS HAIR
	05/20/2013		ZETETIC	PREPARATIONS ENTRY NUMBER EHP-0076949-8 - PHOTOGRAPHS & OASIS SCREEN SHOTS
2013-3166	04/23/2013	ORA/	Chris Kaiser	CONCORD PHARMACY, SUWANEE, GA - (03/01/2013 -
	05/21/2013	ORA/	Kaiser, Chris	04/19/2013)
2013-3167	04/23/2013	ORA/	Mark Greenblatt	PUBLICLY RELEASABLE FIELDS OR TABLES OF DATA RE
	05/21/2013	ORA/	SCRIPPS HOWARD NEWS	PET FOOD COMPLAINTS
		CVM/OCD/	SERVICE	
2013-3168	04/23/2013	FDA/OC/OES/DFOI/	John Reinke	PET AG FORMULAS
	05/21/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	John Reinke	
2013-3169	04/23/2013	CVM/OCD/	Mark Greenblatt	ADVERSE EVENTS REPORTED TO CVM FOR DRUGS GIVEN
	05/21/2013		SCRIPPS HOWARD NEWS	TO ANIMALS OR PETS (01/01/2008 - 04/19/2013)
			SERVICE	
2013-3170	04/23/2013	FDA/OMPT/CDER/GRP/DIDP/	Michael Novod	DIABETES DRUGS - AERS (01/01/2009 - 04/19/2013)
	05/21/2013	FDA/OMPT/CDER/GRP/DIDP/	Nordea Markets	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		

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2013-3171	04/23/2013 05/21/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Stan Kisiel Mercer St Warehouse LLC	INTERNATIONAL FOOD AND CANDY, HIGHTSTOWN, NJ; INTERNATIONAL FOOD AND CANDY, EAST BRUNSWICK, NJ - INSPECTIONS, VIOLATIONS, CORR ETC (01/01/2010 - 04/19/2013)
2013-3172	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	methylnaltrexone Université Joseph Fourier	METHYLNALTREXONE - AERS; SAFETY STUDY NCT 00804141
2013-3173	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/	Amy Kincanon LexisNexis CourtLink Document Retrieval	2013-2535
2013-3174	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Schultz The Dominion Group	NDA 022406 S001, NDA 022406 S003 - SBA, REVIEW
2013-3175	04/23/2013 05/21/2013	ORA/OCI/ ORA/OCI/	Doe J	INVESTIGATION RECS
2013-3176	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K072161
2013-3177	04/23/2013 05/21/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Michelle Masson TRILLIUM HEALTH CARE PRODUCTS INC	SPI PHARMA, GRAND HAVEN, MI - EIR (05/01/2011 - 04/30/2013)
2013-3178	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (04/15/2013 - 04/19/2013)
2013-3179	04/23/2013 05/21/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Michelle Masson TRILLIUM HEALTH CARE PRODUCTS INC	SPI PHARMA, LEWES, DE - EIR (09/01/2012 - 04/30/2013)
2013-3180	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	prashanth jayaram JAYARAM, PRASHANTH	SAREPTA THERAPEUTICS - MINUTES FROM MARCH 2013 TYPE B END-OF-PHASE II MEETINGS
2013-3181	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trupti Shah TAKEDA PHARMACEUTICALS NA INC	INCRETIN-BASED ANTI-DIABETIC AGENT - AERS

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2013-3182	04/23/2013	FDA/OMPT/CDER/GRP/DIDP/	Melissa Burkhart	DESOGESTREL, APRI/DESOGEN - SIDE EFFECTS
	05/21/2013	FDA/OMPT/CDER/GRP/DIDP/	Melissa Burkhart	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3183	04/23/2013	ORA/	Mark Greenblatt	ELECTRONIC LISTING OF ALL PET FOOD MANUFACTURERS INSPECTED BY FDA (01/01/2008 - 04/22/2013)
	05/21/2013	ORA/	SCRIPPS HOWARD NEWS SERVICE	
		ORA/OE/		
		ORA/OE/		
		ORA/ORM/		
		ORA/ORM/		
		FDA/OF/CFSAN/OCD/EOS/		
		FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/		
		FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/		
		FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/		
		FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/		
		FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/		
		FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		
		FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/		
		FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/		
		FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/		
		FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/		
		FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/		
		FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/		
		CVM/OCD/		
2013-3184	04/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patricia Reuter	WYETH INFUSE BONE GRAFT - POST APPROVAL REPORTS

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	05/21/2013		Patricia Reuter	
2013-3185	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	INTERNAL FDA MEMO, EMAIL CORR FOR JAN/FEB 2007 FOR DAN MY-CHU
2013-3186	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	INSPECTIONAL CLASSIFICATION FOR FACTS 808885 BY CDER
2013-3187	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. Burgess BURGESS, BERNIE	BACKGROUND INFORMATION PROVIDED BY CDER DSI TO CONDUCT INSPECTION 808885
2013-3188	04/23/2013 05/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. Burgess BURGESS, BERNIE	BACKGROUND INFORMATION PROVIDED BY CDER DSI FOR FACTS 808885
2013-3189	04/23/2013 05/21/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Stryker Sustainability Solutions STRYKER SUSTAINABILITY SOLUTIONS	RECALL Z-0941-2013 - RECALL RECS
2013-3190	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS - APOGEE AND PERIGEE WITH INTEPRO LITE AND INTExEN LP K082387
2013-3191	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE ANTERIOR AND APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE K082677
2013-3192	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - MINIARC PRECISE SINGLE-INCISION SLING K100807
2013-3193	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE PC APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE, ANTERIOR AND APICAL PROLAPSE REPAIR SYS WITH INTEPRO LITE K111118
2013-3194	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS APOGEE VAULT SUSPENSION SYS K040537
2013-3195	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ PRITZKER OLSEN	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC, MONARC, BIOARC SP, BIOARC TO SLING SYS K041948

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2013-3196	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMD INC - URETHRAL SLING, SURGICAL MESH K051530
2013-3197	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE, AMS ELEVATE APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEXEN LP K082730
2013-3198	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS MINIARC SLING SYS K071902
2013-3199	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	HOLOGIC INC - FULL FIELD DIGITAL X RAY MAMMOGRAPHIC CONTRAST ENHANCED DIGITAL MAMMOGRAPHY SYS K123873
2013-3200	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	HOLOGIC INC - SYS XRAY MAMMOGRAPHIC LORAD AFFIRM BREAST BIOPSY GUIDANCE SYS K122836
2013-3201	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS MINIARC SLING SYS K073703
2013-3202	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	HOLOGIC INC - SYS X RAY MAMMOGRAPIC LORAD DIGITAL SPOT MAMMOGRAPHY SYS K040884
2013-3203	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE PC APICAL AND POSTERIOR PROLAPSE REPAIR SYS WITH INTEPRO LITE, AMS ELEVATE PC ANTERIOIR AND APICAL PROLAPSE SYS WITH INTEPRO LITE K112842
2013-3204	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	MICROSPACE PTY LTD - GENERATOR PULSE PACEMAKER EXTERNAL PROGRAMMABLE CARDIAC STIMULATOR K072200
2013-3205	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - AMS ELEVATE WITH INTEPRO LITE PROLAPSE REPAIR SYS, AMS ELEVATE WITH INTEXEN LP PROLAPSE REPAIR SYS K080185
2013-3206	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHARLES M. HART HART CONSULTING LLC	EP MEDSYSTEMS - GENERATOR PULSE PACEMAKER EXTERNAL PROGRAMMABLE EP 4 CARDIAC STIMULATOR K092913
2013-3207	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SYS, MONARC SYS, MONARC+ SYS, MONARC C SYS K081613
2013-3208	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - APOGEE AND PERIGEE SYS WITH PC COATED INTEPRO LITE K081710
2013-3209	04/23/2013 05/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JAMES FARES NURO PHARMACEUTICALS INC	MYSOLINE NDA 10-401/S10 UNREDACTED

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-3210	04/23/2013 05/21/2013	FDA/OF/CFSAN/OCD/EOS/	CHASTINE12B2563, J	FISH; SHELLFISH - MERCURY CONTENT
2013-3211	04/23/2013 05/21/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JEREMY JOHNSON Traditional Medicinals, Inc.	BI NUTRACEUTICALS, LONG BEACH, CA; ISLANDIA, NY - EIR, 483, RECALL 1/12 TO PRESENT
2013-3212	04/23/2013 05/21/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	JEREMY JOHNSON Traditional Medicinals, Inc.	MARTIN BAUER GROUP, SECAUCUS, NJ; GERMANY - EIR, 483, RECALL 1/12 TO PRESENT
2013-3213	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K013355
2013-3214	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K021263
2013-3215	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K020663
2013-3216	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K MCNABB PRITZKER OLSEN	AMERICAN MEDICAL SYSTEMS INC - MINIARC PRO SINGLE-INCISION SLING SYS K12164
2013-3217	04/23/2013 05/21/2013	FDA/OF/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	WORLEE NATURPRODUKTE GMBH, HAMBURG, GERMANY - EIR, 483, RECALL 1/12 TO PRESENT
2013-3218	04/23/2013 05/21/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OF/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	HIGH QUALITY ORGANICS, RENO, NV - EIR, 483, RECALL 1/12 TO PRESENT
2013-3219	04/23/2013 05/21/2013	FDA/OF/CFSAN/OCD/EOS/	JEREMY JOHNSON Traditional Medicinals, Inc.	MOTHER PARKERS SANDRA TEA & COFFEE LTD, MISSISSAUGA, ONTARIO - EIR, 493, RECALL 1/12 TO PRESENT
2013-3220	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS MONARC SLING SYS K023516
2013-3221	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MESH SYS INC - PELVIC MESH SYS K121612
2013-3222	04/23/2013 05/21/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS K090713
2013-3223	04/23/2013 05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	KELLY K. McNABB PRITZKER OLSEN	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS K011251
2013-3224	04/23/2013	FDA/OC/OES/DFOI/	KELLY K. McNABB	AMERICAN MEDICAL SYS INC - PELVIC MESH PRODUCTS

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	05/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	PRITZKER OLSEN	K040623
2013-3225	04/23/2013	FDA/OMPT/CDER/GRP/DIDP/	DAVID L. ROSEN	OXYTOCIN NDA 02-272/S-014 LBLG
	05/21/2013	FDA/OMPT/CDER/GRP/DIDP/	FOLEY & LARDNER LLP	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3226	04/23/2013	FDA/OF/CFSAN/OCD/EOS/	MERLE ZIMMERMANN	DIETARY SUPPLEMENTS - AER 7/10
	05/21/2013		AMERICAN HERBAL PRODUCTS ASSOCIATION	
2013-3227	04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Luna	K-Y LUBRICATING JELLY - 510K
	05/22/2013		Aphena Pharma Solutions	
2013-3228	04/24/2013	FDA/OMPT/CTP/OD/	Desmond Jenson	2012-8781 UPDATED
	05/22/2013		Tobacco Control Legal Consortium	
2013-3229	04/24/2013	FDA/OMPT/CDER/GRP/DIDP/	Marc C. Sanchez, Esq.	COLLODIAL SILVER - NUMBER OF DEATHS, ALLERGIC REACTIONS, DRUG INTERACTIONS ETC
	05/22/2013	FDA/OMPT/CDER/GRP/DIDP/	Contract In-House Counsel and Consultants, LLC	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3230	04/24/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Scott Fawcett	PHARMATECH, LCC; MEDIPHARM LABORATORIES (06/01/2002 - 04/22/2013)
	05/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Carroll Quality Consult, Inc.	
		FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/		
2013-3231	04/24/2013	FDA/OMPT/CDER/GRP/DIDP/	Rachelle Lyon	XTANDI - CNS AERS
	05/22/2013	FDA/OMPT/CDER/GRP/DIDP/	Janus Capital Group Attn: Rachelle Lyon	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3232	04/24/2013	FDA/OMPT/CDER/GRP/DIDP/	AMY GONZALES	MN PHARMACEUTICALS, INSTANBUL, TURKEY - EIR MAY 2012
	05/22/2013	FDA/OMPT/CDER/GRP/DIDP/	AMGEN INC	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-3233	04/24/2013	FDA/OMPT/CDER/GRP/DIDP/	Joanne Moskovic	SYMBAX - INVESTIGATION RECS
	05/22/2013	FDA/OMPT/CDER/GRP/DIDP/	Moskovic & Associates, Ltd.	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		

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		ORA/OCI/ ORA/OCI/		
2013-3234	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Luna Aphena Pharma Solutions	VAST RESOURCES/TOPCO SALES PERSONAL LUBRICATING JELLY - 510K
2013-3235	04/24/2013 05/22/2013	ORA/ ORA/	AnnMarie Beattie Harmonized Customs Brokers, Inc.	ENTRY G76-0129969-4 - LAB RESULTS
2013-3236	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim M. Lohnes ORCHID DESIGN	K122470
2013-3237	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	GENESIS RETAIL GENESIS RETAIL INC	K12171
2013-3238	04/24/2013 05/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tomisha LeClair LECLAIR, TOMISHA	ZOFRAN - AERS
2013-3239	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K041393
2013-3240	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Yuta Kawakatsu TOYOBO U.S.A., INC.	K103081
2013-3241	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K953509
2013-3242	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K051956
2013-3243	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070874
2013-3244	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barry Callahan RJL SYSTEMS	K874361
2013-3245	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121426
2013-3246	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K960455
2013-3247	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K965241
2013-3248	04/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson	K993655

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	05/22/2013		FOI Services, Inc.	
2013-3249	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - APOGEE VAULT SUSPENSION SYS K040537
2013-3250	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SYS; MONARC SYS; MONARC+SYS, ETC K081613
2013-3251	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - BIOARC SP SLING KIT K030123
2013-3252	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - IN-FAST BONE SCREW SYS K011910
2013-3253	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K013355
2013-3254	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K011251
2013-3255	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SINGLE INCISION SLING SYS K070065
2013-3256	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K021263
2013-3257	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - SPARC SLING SYS K020663
2013-3258	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEM INC - MINIARC SLING SYS K071902
2013-3259	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - PERIGE TM SYS K040623
2013-3260	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MONARC SLING SYS K023516
2013-3261	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - ELEVATE PROLAPSE REPAIR SYS WITH PC COATED INTEPRO LITE K090713
2013-3262	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - APOGEE & PERIGEE SYS WITH PC COATED INTEPRO LITE K081710

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		FDA/OC/OES/DFOI/		
2013-3263	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYS INC - SPARC, MONARC BIOARC SP & BIOARC TO SLING SYS K041948
2013-3264	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MINIARC PRECISE T SINGLE-INCISION SLING K0100807
2013-3265	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MONARC & BIOARC TO SUBFASCIAL HAMMOCKS K051530
2013-3266	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	AMERICAN MEDICAL SYSTEMS INC - MINIARC SLING SYSTEM K073703
2013-3267	04/24/2013 05/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	PATHEON PHARMS, CINCINNATI, OH - QAP
2013-3268	04/24/2013 05/22/2013	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	JAMES DORE DORE DEUTSCHER LAW GROUP PLLC	TOCOMA RADIOLOGICAL ASSOCIATES , LAKEWOOD, WA - INSPS 1999 TO 2010
2013-3269	04/24/2013 05/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Sinem Tan MN Pharmaceuticals-Mustafa Nevzat Ilac	MUSTAFA NEVZAT - EIR 04/20/12 TO 05/03/12
2013-3270	04/24/2013 05/22/2013	ORA/OCI/ ORA/OCI/	Roger Farmer Nation Treasury Employees Union	INTERNAL AFFAIRS INVESTIGATION
2013-3271	04/24/2013 05/22/2013	ORA/ ORA/	Anthony Sansone Anthony M. Sansone	FOOD SAMPLE 798264 - DETENTION RECS
2013-3272	04/24/2013 05/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Karen Seta-Aust Camargo Pharmaceutical Services	FDA STAFF MANUAL GUIDE 4850.7
2013-3273	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chiara Cunico Brainlab AG	BRAINLAB - EIR (01/01/2008 - 12/31/2012)
2013-3274	04/24/2013 05/22/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Aida Durmo Bosnalijek d.d.	IND-SWIFT, PUNJAB, INDIA - EIR (01/01/2011 - 04/24/2013)

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2013-3275	04/24/2013 05/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Mario Vesnaver Mario Vesnaver	LENSX - RESPONSE TO WARNING LETTER
2013-3276	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Keller CooperSurgical, Inc	K110288
2013-3277	04/24/2013 05/22/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Lauren Farruggia Hyman, Phelps and McNamara	CHATTEM, INC - WARNING LETTER RECS
2013-3278	04/24/2013 05/22/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	CRAIG ROUSH ROCHLINE INDUSTRIES	PAXICO LLC, BATAVIA, OH - EIRS, 483S, CORR 1/08 TO PRESENT
2013-3279	04/24/2013 05/22/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ ORA/ ORA/	JACK WEATHERLY ARKANSAS DEMOCRAT GAZETTE	2004-DAL-WL-02 - RECS
2013-3280	04/24/2013 05/22/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Doe J	CMPLNT
2013-3281	04/24/2013 05/22/2013	FDA/OF/CFSAN/OCD/EOS/	LAURA J STEVENS PURDUE UNIV/NUTRITION SCIENCE DEPT	NATIONAL RESEARCH COUNCIL - SURVEY OF INDUSTRY ON THE USE OF FOOD ADDITIVES VOL 3 10/31/79
2013-3282	04/24/2013 05/22/2013	FDA/OO/OHR/	REICHLER, VIRGIL D	HHS-FDA-ORA-MP-13-861909 - RESUMES
2013-3283	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113527
2013-3284	04/24/2013 05/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kathleen Selover Selover, Kathleen	K022807
2013-3285	04/24/2013 05/22/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Sahil Bhatia Manning and Napier Advisors	COOPER COMPANIES, COOPERVISION, COOPER SURGICAL - 483 (01/01/2012 - 04/24/2013)
2013-3286	04/24/2013	FDA/OGROP/ORA/CE-FO/DET-	Angelia Slayton	JHP PHARMACEUTICALS, ROCHESTER, MI - EIR, 483

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	05/22/2013	DO/DET-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	INC RESEARCH CONSULTING & SUBMISSIONS	01/01/11 TO 3/20/13
2013-3287	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eagle Pharmaceuticals, Inc. Eagle Pharmaceuticals, Inc.	CIPLA LIMITED UNIT V, VIII, AND IX VERNA INDUSTRIAL ESTATE, VERNA, COA, INDIA - EIR, 483 (01/01/2010 - 05/31/2013)
2013-3288	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alexander M M Shepherd MD PhD UTHSCSA	OXYCODONE - AERS
2013-3289	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K063345
2013-3290	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K042961
2013-3291	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Kiblinger DiaPharma	K103555
2013-3292	04/25/2013 05/23/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	Joshua Malamud Hyman, Phelps & McNamara, P.C.	ICON DEVELOPMENT SOLUTIONS - 483, EIR (01/01/2008 - 04/24/2013)
2013-3293	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Benjamin Burgin Salix Pharmaceuticals, Inc.	NDA 21908 S011
2013-3294	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brienne Kugler Morgan Stanley	JAKAFI - AERS
2013-3295	04/25/2013 05/23/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Fulbright & Jaworski FULBRIGHT & JAWORSKI LLP	DERMA SCIENCE, PRINCETON, NJ - WARNING LETTERS, EIR, 483 ETC (01/01/2007 - 04/24/2013)
2013-3296	04/25/2013 05/23/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Jeanne Whalen WALL STREET JOURNAL	NOVARTIS, LINCOLN, NE - 483 (01/01/2011 - 04/24/2013)
2013-3297	04/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-1867 REQUEST LETTER

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	05/23/2013		MERCK & CO., INC.	
2013-3298	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2089, 2013-2092, 2013-2094 - REQUEST LETTER
2013-3299	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1690 REQUEST LETTER
2013-3300	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	201300165 MERCK & CO., INC.	2013-1842 REQUEST LETTER
2013-3301	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1760 REQUEST LETTER
2013-3302	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1763 REQUEST LETTER
2013-3303	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2295 REQUEST LETTER
2013-3304	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1654 REQUEST LETTER
2013-3305	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1662 REQUEST LETTER
2013-3306	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1693 REQUEST LETTER
2013-3307	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2251 REQUEST LETTER
2013-3308	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2421 REQUEST LETTER
2013-3309	04/25/2013 05/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	vinu Self	PEANUT OIL/PROTEIN IN VACCINES
2013-3310	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Francisco Polonio Laboratorios Lesvi, S.L.	ALGORITHM PHARMA INC, CANADA - 483 NOVEMBER 2012
2013-3311	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Card none	K082819, K072870
2013-3312	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202497

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2013-3313	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Roger Golden Roger N. Golden, a Professional Corporation	RICHWAY, INC, NEVADA - FOOD INSPECTIONS, REGISTRATION
2013-3314	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Roger N. Golden Roger N. Golden, A Prof. Corp.	ASIACORP, CALIFORNIA - FOOD INSPECTIONS, REGISTRATION
2013-3315	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/	WILLIAM A OLSON, Ph.D. Center for Regulatory Services, Inc.	IMPACT MODIFIED NYLON MXD-6 RESINS - PETITIONS
2013-3316	04/25/2013 05/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	MINUTES FROM SEREPTA THERAPEUTICS TYPE B END OF PHASE II MTGS 3/13
2013-3317	04/25/2013 05/23/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ALEXION PHARMACEUTICALS, CHESHIRE, CT - EIR, 483, WARNING LTR 1/11 TO PRESENT
2013-3318	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD. FAVUS INSTITUTIONAL RESEARCH LLC	2013-1813
2013-3319	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/	ELIZABETH SWEIS INTERTEK	FAP 9A4175
2013-3320	04/25/2013 05/23/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	BRIAN WILLIAMSON JCB Laboratories	JCB LABS, WICHITA, KS - EIR 2/12
2013-3321	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	LAW OFFICES OF RONALD A MARRON	UNREDACTED RECORDS
2013-3322	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	SYDNEY FREEDBERG BLOOMBERG NEWS	CHALRES OSHAUGHNESSY WARNING LTR
2013-3323	04/25/2013 05/23/2013	FDA/OC/OES/DFOI/	LAW OFFICES OF RONALD A MARRON	UNREDACTED RECS
2013-3324	04/25/2013	FDA/OC/OES/DFOI/		UNREDACTED RECS

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	05/23/2013		LAW OFFICES OF RONALD A MARRON	
2013-3325	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FLYNN P. CAREY MITCHELL STEIN CAREY PC	THERMO LIFE INTL LLC - RECALL, INVESTIGATIONS
2013-3326	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	FLYNN P. CAREY GALLAGHER & KENNEDY PA	THERMO LIFE - CORR 1/00 TO 12/11
2013-3327	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AL-MUJAHIDIN 103968, MUHAMMAD	LIST OF VITAMINS; HALDON, THORAZINE, BOSPAR - AER
2013-3328	04/25/2013 05/23/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RONALD J LANGA PA	SYNTHES USA HQ, WEST CHESTER, PA - CLICK X 3D POLYAXIAL HEADS; PEDICLE SCREWS; N HANCE RODS CMLNT
2013-3329	04/25/2013 05/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	NIEVE ANJOMI RODMAN LAW GROUP LLC	PROSTATE 63 CANCER DIAGNOSTIC TEST K050063
2013-3330	04/25/2013 05/23/2013	FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/	PAIGE TOMASELLI CENTER FOR FOOD SAFETY	REN O SAL TABLETS ROXARSONE, ZOCO POULTRY TABLETS, KORUM IMPROVED FORMULA ETC - SAFETY & EFFECTIVENESS STUDIES, CMLNTS 2009 TO PRESENT
2013-3331	04/25/2013 05/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A. THURSTON, Jr. THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S-009; 20-971/S-013
2013-3332	04/25/2013 05/23/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	BEN EISLER CBS This Morning	QUINTILES INC - AER 2009 TO PRESENT
2013-3333	04/26/2013 05/24/2013	FDA/OC/OES/DFOI/	Jeanne Whalen WALL STREET JOURNAL	NOVARTIS - FOIA REQUESTS (01/01/2011 - 04/25/2013)

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2013-3334	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Shire Human Genetic Therapies, Lexington, MA
2013-3335	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Amgen Inc, Woburn, MA.
2013-3336	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Bristol-Meyers-Squibb, Devens, MA
2013-3337	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Cubist Pharmaceuticals, Lexington, MA
2013-3338	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Amgen Inc, West Greenwich, RI
2013-3339	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Biogen Idec, Cambridge, MA
2013-3340	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Alexion Pharmaceuticals, Smithfield, RI
2013-3341	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: AMAG Pharmaceuticals, Inc., Cambridge, MA
2013-3342	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Abbott Laboratories, Worcester, MA
2013-3343	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Lonza Biologics, Inc., Newington, NH
2013-3344	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme, Allston, MA
2013-3345	04/26/2013 05/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Dynamit Nobel GmbH, Kalkstrasse, Leverkusen, Germany

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2013-3346	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Labor L & S AG, Bad Bocklet-Grossenbrach, Germany
2013-3347	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: ImmunoGen, Norwood, MA
2013-3348	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme, Northborough, MA
2013-3349	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Vertex Pharmaceuticals, Cambridge, MA
2013-3350	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Alexion Pharmaceuticals, Cheshire, CT
2013-3351	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Micronisierungs-Kontor Oberrot GmbH (MCKO, Oberot, Germany)
2013-3352	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: AstraZeneca Pharmaceuticals LP, Westborough, MA
2013-3353	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme, Cambridge, MA
2013-3354	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Lonza Group Ltd., Hopkinton, MA
2013-3355	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Infinity Pharmaceuticals, Cambridge, MA
2013-3356	04/26/2013 05/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Stryker Biotech, Hopkinton, MA

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2013-3357	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Merrimack Pharmaceuticals Inc., Cambridge, MA
2013-3358	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Genzyme Science Center, Framingham, MA
2013-3359	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA16131
2013-3360	04/26/2013 05/24/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firm's available correspondence from August 1, 2012 to January 31, 2013 for: Millenium (Takeda), Cambridge, MA
2013-3361	04/26/2013 05/24/2013	FDA/OF/CFSAN/OCD/EOS/	DEVON HILL Keller and Heckman LLP	EASTMAN CHEMICAL CO - FCN 224, FCN 440, FCN 597 TOXICOLOGY MEMO
2013-3362	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Meade, Doris	NORTHEAST PHARMACEUTICAL GROUP CO LTD, LIAONING PROVINCE, CHINA - 483 7/12
2013-3363	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CURTIS A THURSTON JR THURSTON LAW OFFICES	SEPTOCAINE NDA 20-971/S009,S013 - DEAR HEALTH CARE PROFESSIONAL LTR
2013-3364	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GALDERMA LABS LP - ADAPALENE (DIFFERIN) NDA 20-338 SBA
2013-3365	04/26/2013 05/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY J STANIFORD NIPRO Diagnostics	MW5029708
2013-3366	04/26/2013 05/24/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-2507
2013-3367	04/26/2013 05/24/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS US LLP	2013-2804

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2013-3368	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS T67081, KEITH	UNIMED - MARINOL SBA, PSYCHOACTIVE COMPONENT OF THC, MFR ADDRESS, ETC
2013-3369	04/26/2013 05/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW5029745
2013-3370	04/26/2013 05/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alan Schwartz Schwartz Imaging	ULTRASOUND STANDOFF PAD DEVICE - MEDICAL SAFETY DEVICE SHEET
2013-3371	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tony Fiorino Greywall Asset Management	EXPAREL - AERS
2013-3372	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ranbaxy Ranbaxy Inc.	ANDA 062479
2013-3373	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Francisco Polonio Laboratorios Lesvi, S.L.	Algorithme Pharma Inc, Canada - 483 01/2011
2013-3374	04/26/2013 05/24/2013	FDA/OF/CFSAN/OCD/EOS/	EYASSU G ABEGAZ PHD AJINOMOTO NORTH AMERICA INC	ASPARTAME - CAERS 1995 TO 2012
2013-3375	04/26/2013 05/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pat Walicke MD, PhD SteadyMed Therapeutics	REMODULIN - MEDWATCH REPORTS
2013-3376	04/26/2013 05/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JESSICA WICHA BAKER & MCKENZIE	NAVARO PECAN COMPANY INC, CORSICANA, TX; CAMILLA COMMODITY SERVICES INC, CAMILLA, GA - EIRS. 483S CORR, ETC 2007 TO PRESENT
2013-3377	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALAIN GUILLAUMOT LANDANGER SA	K014207
2013-3378	04/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Epimed International - For Wallach	K854334

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	05/28/2013		PainBlocker Epimed International, Inc.	
2013-3379	04/29/2013 05/28/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Todd Wendt Seatech Corporation	ENTRY 603-1096062-4
2013-3380	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ashley tuan Nexis Vision	K083921
2013-3381	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	FOIA REQUESTS FOR CFSAN (04/01/2013 - 04/26/2013)
2013-3382	04/29/2013 05/28/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Rachel Johnson FOI Services, Inc.	H LEE MOFFITT CANCER CENTER, TAMPA, FL - EIR
2013-3383	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-2260, 2013-2273
2013-3384	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephanie Edwin St. John Hospital and Medical Center	RIVAROXABAN - AERS
2013-3385	04/29/2013 05/28/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Stephanie Fullard Porex Corporation	POREX CORPORATION - EIR (11/28/2012 - 02/20/2013)
2013-3386	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ABUSE DETERRENCE OR TAMPER RESISTENCE TESTING TO SUPPORT APPROVAL OF NEW DRUG APPLICATION FOR OXYCONTIN
2013-3387	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Newman Law Offices of Jeffrey A. Newman & Associates	LC BEAD MICROSPHERES, BEADBLOCK MICROSPHERE - ADVERSE EVENTS 2006 TO PRESENT
2013-3388	04/29/2013 05/28/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Jennifer C. Smith-Parker BIOPHARM INSIGHT	ALEXION PHARMACEUTICALS - RESPONSES TO WARNING LETTER ISSUED 03/22/2013
2013-3389	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeffrey Newman Law Offices of Jeffrey A. Newman & Associates	DUXORUBICIN HYDROCHLORIDE - AERS JANUARY 2006 TO PRESENT
2013-3390	04/29/2013	ORA/ORM/	Querida Anderson	CLINICAL INVESTIGATIONS - LIST OF INSPECTIONS

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	05/28/2013	ORA/ORM/ ORA/OE/ ORA/OE/	BIOPHARM INSIGHT	(01/01/2013 - 03/31/2013)
2013-3391	04/29/2013 05/28/2013	FDA/OF/CFSAN/OCD/EOS/	Marcella Garsetti Unilever Canada	DATA ON MARGARINES AND SPREADS
2013-3392	04/29/2013 05/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stephen Teti Teti, Stephen	VENTRUS BIOSCIENCES, INC - RECS AND COMM WITH FDA RE IFERANSERIN, VEN 309 ETC
2013-3393	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/	TURIEL, MIWTCHELL R	EXCEDRIN'S REMOVAL FROM THE SHELVES - RECS
2013-3394	04/29/2013 05/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ann Waterhouse HILL ROM	LUNG ASSIST INC - K120277
2013-3395	04/29/2013 05/28/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	MIKE BYROM BIOEDEN INC	COOK GENERAL BIO TECHNOLOGY LLC, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 2010 TO PRESENT
2013-3396	04/29/2013 05/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DHSDHSNKK UPSFHYE SEYFARTH SHAW LLP	JANSSEN PHARMS - NUCYNTA NDA 22-304 FORMS 356(H), 3542, 3542(A), JAPEUTADOL HCL ETC
2013-3397	04/29/2013 05/28/2013	FDA/OF/CFSAN/OCD/EOS/	JEFF GREAVES FOOD INGREDIENT SOLUTIONS LLC	GNT - SPIRULINA CONCENTRATE PETITION
2013-3398	04/29/2013 05/28/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	JEFF GREAVES FOOD INGREDIENT SOLUTIONS LLC	MARS INC - SPIRULINA BLUE PETITION
2013-3399	04/29/2013 05/28/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	BRENDAN J FLAHERTY PRITZKER OLSEN	WHOLE FOODS, EAST LIBERTY, PA - PERRIN EDEL DE CLERON CHEESE FOODBORNE PATHOGEN OUTBREAK TESTING, INSP RPTS, ENFORCEMENT ACTIONS, ETC 1/11 TO PRESENT
2013-3400	04/29/2013 05/28/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	MICHAEL J VILLEGGIANTE WELTIN STREB & WELTIN	MOON FISHERY (INDIA) PVT LTD, MOON MARINE (USA) CORP, MOON MARINE INTERNATIONAL CO LTD, ETC - RPTS, CORR 1/08 TO PRESENT; INSPS 2010 TO PRESENT, ETC
2013-3401	04/29/2013 05/28/2013	FDA/OF/CFSAN/OCD/EOS/	CHRISTOPHER LEN NY/NJ BAYKEEPER	NJ SHELLFISH PROGRAM - ANNUAL PROGRAM EVALUATION RPTS FY2009

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2013-3402	04/29/2013 05/28/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	PATRICIA L REGENYE Celgene Corporation	SCOTT SMITH, LOYOLA UNIV CHICAGO, MAYWOOD, IL - 483S 5/11 TO PRESENT
2013-3403	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	CORR BTWN DR. DOV LINZER & DIVISION OF SCIENTIFIC INVESTIGATIONS
2013-3404	04/29/2013 05/28/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Doe J	ROCHE MOLECULAR SYSTEMS, ALAMEDA, CA - INVESTIGATOR'S INTERIM AND FINAL RPTS, CORR 2003
2013-3405	04/29/2013 05/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHIPMAN, KIM	ISRS 4668141, 4532649, 7748365
2013-3406	04/29/2013 05/28/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Doe J	CHILDREN'S HOSPITAL OAKLAND RESEARCH INSTITUTE (CHORI) - INVESTIGATOR'S INTERIM AND FINAL RPTS, CORR
2013-3407	04/29/2013 05/28/2013	FDA/OMPT/CTP/OD/	CHARLES CELESTE EAS CONSULTING GROUP LLC	TOBACCO ESTABLISHMENTS REGISTERED WITH THE FDA PER THE REQUIREMENTS UNDER SECTION 905 OF THE ACT
2013-3408	04/29/2013 05/28/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCDEOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FOOD FACILITIES REGISTERED WITH THE FDA AS PER THE REQUIREMENTS UNDER THE FD&C ACT, BIOTERRORISM ACT AND FSMA
2013-3409	04/30/2013 05/29/2013	FDA/OC/OES/DFOI/	Jake McDowell The Weinberg Group	FOIA DAILY LOG (01/01/2010 - 04/01/2013)
2013-3410	04/30/2013 05/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Muhammad arif SIMPLE DIAGNOSTICS	K121224
2013-3411	04/30/2013 05/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable EIR for the April 2012 for inspection of: Nycomed GmbH: A Takeda Company, Robert-Bosch Strasse 8, Singen (Hohentwiel), Baden-Wuerttemberg 78224, Germany
2013-3412	04/30/2013 05/29/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms correspondence from January 1, 2005 to December 31, 2010 for: Colorado State University, Endocrine Laboratory, Colorado
2013-3413	04/30/2013 05/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the approval letter, labeling, medical review, chemistry review, pharmacology review, statistical review, and all other releasable documents for: Invega (paliperidone), NDA 21-999 S-004, manufactured by Ortho McNeil Janssen, and approved

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		FDA/OMPT/CDER/GRP/DIDP/		12/22/09
2013-3414	04/30/2013 05/29/2013	FDA/OF/CFSAN/OCD/EOS/	Wu Chen Wu, Chen	SANTE INTERNATIONAL - ADVERSE EVENTS (04/01/1985 - 04/27/2013)
2013-3415	04/30/2013 05/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Deval Patel STRYKER CORP	K050766
2013-3416	04/30/2013 05/29/2013	FDA/OC/OES/	Jim McElhatton FEDERAL TIMES	FDA SEQUESTRATION PLAN (10/01/2012 - 04/26/2013)
2013-3417	04/30/2013 05/29/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms correspondence from January 1, 2005 to December 31, 2010 for: Research Pathology Services, New Britain, Pennsylvania
2013-3418	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Terrie Cowley THE TMJ ASSOCIATION, LTD	TMJ CONCEPTS, INC, TMJ MEDICAL, INC, BIOMET MICROFIXATION - MOST RECENT INSPECTION RECS, NUMBER OF HDE REQUESTED (02/07/2010 - 04/26/2013)
2013-3419	04/30/2013 05/30/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	TYLER KENYON NORTHCOAST RESEARCH	HILL ROM HOLDINGS, BATESVILLE, IN; INTEGRA LIFE SCIENCES MGMT, ANASCO, PR - RESP LTR 3/12
2013-3420	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - TIFFINY BURROWS INVESTIGATION
2013-3421	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF JULIAN OMIDI
2013-3422	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF MICHAEL OMIDI
2013-3423	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF MORTON ELLIOTT ALPERT
2013-3424	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF TOP SURGEONS LLC

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2013-3425	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF BAKERSFIELD SURGERY INSTITUTE INC
2013-3426	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF WOODLAKE AMBULATORY SURGERY CTR
2013-3427	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF NEW LIFE SURGERY CTR
2013-3428	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION ALMONT AMBULATORY SURGERY CTR
2013-3429	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY LOS ANGELES - INVESTIGATION OF BEVERLY HILLS SURGICAL CTR
2013-3430	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF VALLEY SURGICAL CTR LLC
2013-3431	04/30/2013 05/29/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	David Mangione Govzilla, Inc.	BEN VENUE LABORATORIES, BEDFORD, OH - EIR, 483 (03/29/2013 - 03/29/2013)
2013-3432	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF 1800 GET SLIM
2013-3433	04/30/2013 05/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alejandro Gonzalez Della Valle, MD Alejandro Gonzalez Della Valle, MD	ZIMMER LONGEVITY - ADDITIONAL MAUDE INFORMATION
2013-3434	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF SAN DIEGO AMBULATORY CTR LLC
2013-3435	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION OF COSMOPOLITIAN PLASTIC & RECONSTRUCTION SURGERY
2013-3436	04/30/2013 05/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION PALMDALE AMBULATORY CTR
2013-3437	04/30/2013 05/29/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shin Kang WELLS FARGO	GILEAD SCIENCES - 483, EIR, WARNING LETTER (04/01/2012 - 04/29/2013)

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		FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/		
2013-3438	04/30/2013 05/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	P. MOLLY FORD MARANGA MORGENSTERN LAW CORP	VALLEY SURGICAL CTR VS COUNTY OF LOS ANGELES - INVESTIGATION VALENCIA AMBULATORY CTR LLC
2013-3439	04/30/2013 05/29/2013	FDA/OC/OES/DFOI/	PHINNY, C WENDY	TEVA PHARMACEUTICALS - PALONOSETRON HYDROCHLORIDE INJECTION NDA 202-224 CORR
2013-3440	04/30/2013 05/29/2013	FDA/OC/OES/DFOI/	Jeanne Whalen Wall Street Journal and Dow Jones	2013-2212; 2012-1390; 2012-5139
2013-3441	04/30/2013 05/29/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	b. Burgess BURGESS, BERNIE	FACTS ASSIGNMENT ISSUED BY CDER GOOD CLINICAL PRACTICE TO LOS
2013-3442	04/30/2013 05/29/2013	ORA/ ORA/ FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Doe J	INDIVIDUAL RECS
2013-3443	04/30/2013 05/29/2013	FDA/OC/OES/DDM/	Kathy Osgerby Taylor Wessing LLP	DISCUSSION FOR DESIGNING CLINICAL PROGRAMS FOR DEVELOPING DRUGS, DEVICES, OR BIOLOGICAL PRODUCTS ETC
2013-3444	04/30/2013 05/29/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Ray Jozwik Coeur Inc.	K003398

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-3445	04/30/2013 05/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Erin Hendrick GRADY HEALTH SYSTEM	ABELCET - MEDWATCH REPORTS
2013-3446	04/30/2013 05/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Denise Miller Denise Miller	PHENTERMINE - AERS
2013-3447	04/30/2013 05/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2013-3448	05/01/2013 05/30/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	DONNA BONFIGHO RHODIA INC	RHODIA INC, SPARTANBURG, SC - EIR 11/28/12-12/5/12
2013-3449	05/01/2013 05/30/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	BETTINA CAMCIGIL Humane Society of the United States	RICHARD J CZIMER JR, CZIMER FOODS INC, HOMER GLEN, IL - INVESTIGATIONS, LICENSING, INSPS, ETC
2013-3450	05/01/2013 05/30/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	DEBRA A DULYN MURNANE BRANDT	CUT FRUIT EXPRESS INC, INVER GROVE HEIGHTS, MN - INSPS, RECALLS, WARNING LTRS, ETC
2013-3451	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERZ PHARMS - XEOMIN (INCOBOTULINUMTOXIN A) BLA 125360/007
2013-3452	05/01/2013 05/30/2013	FDA/OF/CFSAN/OCDE/EOS/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	WILLIAMS SR, GARY	PLASTIC BAGS, PLASTIC WRAP USED TO STORE AND SERVE FOOD - RECALLS, INVESTIGATIONS, COMPLNTS, ETC
2013-3453	05/01/2013 05/30/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	MICHAEL D LEVIN HEALTH BUSINESS STRATEGIES	CBA PHARMA INC, LEXINGTON, KY - EIRS, 483S, WARNING LTRS, ETC
2013-3454	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	RANEXA - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3455	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DISSANAYAKE, SANJEEVA	ASTRAZENACA - LONG-ACTING BETA-AGONISTS BRIEFING DOCUMENTATION FOR THE JOINT A/C 12/08
2013-3456	05/01/2013 05/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE BIOLOGICALS, RIXENSART, BELGIUM - 483
2013-3457	05/01/2013 05/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	KIM HENDERSON SANOFI PASTEUR	GLAXOSMITHKLINE BIOLOGICALS, DRESDEN, GERMANY - 483 2012
2013-3458	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	SIMVISTATIN WITH VORICONAZOLE - AERS
2013-3459	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	VFEND (VORICONAZOLE) WITH VYTORIN - AERS
2013-3460	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	VFEND (VORICONAZOLE) WITH VYTORIN - AERS
2013-3461	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	SIMIVSTATIN - APRVL RECS, DEVELOPMENT, EVALUATION, ETC
2013-3462	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	EZETIMIBE WITH VORICONAZOLE - DEVELOPMENT, EVALUATION, APRVL, ETC
2013-3463	05/01/2013 06/24/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	AMS Health Sciences LLC AMS Health Sciences	COMPLAINT 1600095

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2013-3464	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	NDA 050684
2013-3465	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	NDA 050684
2013-3466	05/01/2013 06/24/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	AMS Health Sciences LLC AMS Health Sciences	COMPLAINT 164176
2013-3467	05/01/2013 05/30/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Lesley Valle Boehringer Ingelheim	LOYOLA UNIVERSITY MEDICAL CENTER, LOYOLA UNIVERSITY, CHICAGO, IL - 483 (04/01/1980 - 04/30/2013)
2013-3468	05/01/2013 05/30/2013	CVM/OCD/	Ruth Lamley Bayer HealthCare LLC Animal Health	NADA 034254
2013-3469	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jill Woods McRoberts Security Technologies	MEDWATCH 5025529
2013-3470	05/01/2013 05/30/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Michele Sinoway Lachman Consultants	CAPRICORN PHARMA INC - RESPONSE TO WARNING LETTER (04/21/2010 - 03/15/2011)
2013-3471	05/01/2013 05/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 4/1-30/2013
2013-3472	05/01/2013 05/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS
2013-3473	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS ASSESSMENT FOR BYDUREON, FORTEO
2013-3474	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	REMS ASSESSMENT FOR ACTEMRA, ARCAPTA NEOHALER, DULERA, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3475	05/01/2013 06/04/2013	ORA/ ORA/	fiona nelson wedderspoon organic USA	MANUKA HONEY, WEDDERSPOON ORGANIC - COMPLAINTS (01/01/2011 - 01/01/2013)
2013-3476	05/01/2013 05/30/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Infab Corporation Infab Corporation	BLOX-R CORPORATION - INVESTIGATION RECS (01/01/2013 - 04/30/2013)
2013-3477	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELODIE PALYSWIT Camicas Productions	BOTOX - AERS
2013-3478	05/01/2013 05/30/2013	ORA/ORM/ ORA/ORM/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess bernie burgess	LIST OF FOR-CAUSE INSPECTIONS CONDUCTED BY LOS-DO 2006, 2007
2013-3479	05/01/2013 05/30/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b burgess bernie burgess	FACTS ASSIGNMENT 808885 - LETTER TO VA PROJECT OFFICER
2013-3480	05/01/2013 05/30/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Alex Nussbaum HEALTHCOR MANAGEMENT LP	GILEAD SCIENCES - 483 LAST 12 MONTHS; COMPLETE RESPONSE LETTER; FOIA REQUESTS
2013-3481	05/01/2013 05/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 201281

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-3482	05/01/2013 05/30/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Francine Vero Towne, Ryan & Partners, PC	NOVASURE INPEDANCE CONTROLLED ENDOMETRIAL ABLATION SYSTEM - CORR WITH FDA, NOVACEPT, INC, HOLOGIC TO NATHAN LITTAUER HOSPITAL OR DR ANDREW SAMACH
2013-3483	05/02/2013 05/31/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	GIOVANNI PARRINELLO, Ph.D. MACLEOD PHARMACEUTICALS INC	MACLEOD PHARMACEUTICALS - EIR 12/18 TO 12/21/12
2013-3484	05/02/2013 05/31/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	SHERI O. COVINGTON K&L GATES	HEM CARE OF OREGON INC - WARNING LTR, 483 2011 TO PRESENT
2013-3485	05/02/2013 05/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	lisa suchar self-employed	NDA 202813 - SBA
2013-3486	05/02/2013 05/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Deborah Sontag THE NEW YORK TIMES	SUBOXONE - CASE REPORTS 7247578 766 7903972 8169325 ETC
2013-3487	05/02/2013 05/31/2013	ORA/ ORA/ ORA/ORM/ ORA/ORM/ ORA/OE/ ORA/OE/	Debra Dressel Dressel, Debra A	LIST OF APPLE CIDER FACILITIES WITH HACCP INSPECTIONS LAST FIVE YEARS; VIOLATIONS CITED
2013-3488	05/02/2013 05/31/2013	FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/	Kyle Herink Kemin Industries, Inc.	FAP FOR SELENIUM YEAST SUBMITTED BY ALLTECH, INC
2013-3489	05/02/2013 06/05/2013	FDA/OC/OES/	Emily Flitter Reuters News	COMMISSIONER MARGARET HAMBURG - AGENDA, CALENDAR, APPOINTMENTS ETC (01/01/2011 - 05/01/2013)
2013-3490	05/02/2013 05/31/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Kim Barton Watson Laboratories, Inc.	WARNER CHILCOTT CO, LLC, FAJARDO, PR - EIR (03/01/2013 - 04/30/2013)
2013-3491	05/02/2013 05/31/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection report for the September 2012 inspection for: University of Arkansas for Medical Sciences (UAMS) Myeloma Institute for Research & Therapy, Little Rock, AR
2013-3492	05/02/2013	FDA/OF/CFSAN/OCD/EOS/	Carmon Yusten	CREATINE ETHYL ESTHER HCI - NEW DIETARY

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	05/31/2013		Yusten, Carmon D	INGREDIANT RECS
2013-3493	05/02/2013 05/31/2013	FDA/OC/OES/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OL/	Emily Flitter Reuters News	ETEPLIRSEN, SAREPTA THERAPEUTICS - COMMUNICATIONS (1/01/2011 - 05/01/2013)
2013-3494	05/02/2013 05/31/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA DAILY LOG (04/01/2013 - 04/05/2013)
2013-3495	05/02/2013 05/31/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MELANIE COURTOT TERRY FOX LABORATORY BCCRC	BOTSIS - VAERS
2013-3496	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	EDWARD F BRUNO BRUNO & WEINER	PHYSICIAN LICENSED OR PRACTICING MEDICINE IN THE US REGARDING BOTOX PURCHASES - LTR, NOTICE, CEASE & DESIST ORDER, ETC 11/30/12, 1/13/12
2013-3497	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LOLLAR, EVELYN	DIPHENOXYLATE HCL, ATROPINE SULFATE TABS - AERS
2013-3498	05/03/2013 06/03/2013	FDA/OC/OES/DFOI/	MICHAEL P MANAPOL BRIAN D WITZER INC	SOLODYN (MINOCYCLINE HCL) NDA 50-808 - ISRS 4172850, 6464532, 6638697, ETC 4/23/08 TO 4/23/13
2013-3499	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIO A INCHIOSA NEW YORK MEDICAL COLLEGE/DEPT OF PHARMACOLOGY	ISRS 4054799, 4133493, 6077511
2013-3500	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRANCIS J MARTIN DELPOR INC	ALZA CORP (JOHNSON & JOHNSON PHARMS) - VIADUR (LEUPROLIDE ACETATE IMPLANT) NDA 21-088 SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3501	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	G SRINIVAS ZYDUS PHARMACEUTICALS USA INC	BAUSCH & LOMB - FLUNISOLIDE NASAL SPRAY ANDA 74-805 SBA
2013-3502	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	HYDROCODONE - AERS
2013-3503	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrian Chowdhary UCB Pharma Ltd	CATALENT, BRUSSELS, BELGIUM - MOST RECENT EIR
2013-3504	05/03/2013 06/03/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	2011-5643, 2012-1704, 2012-5451 ETC
2013-3505	05/03/2013 06/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21196 PRELIMINARY CLINICAL SAFETY REVIEW
2013-3506	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K123901
2013-3507	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics In.	K063391
2013-3508	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123700
2013-3509	05/03/2013 06/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michele Sacman Sacman, Michele	TARGOS MOLECULAR PATHOLOGY GMBH, KASSEL, GERMANY - EIR (08/01/2010 - 08/31/2010)
2013-3510	05/03/2013	FDA/OMPT/CBER/OCOD/DDOM/	PATRICK KELLY	INDIVIDUAL RECS (CERTIFIED)

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	06/03/2013	ALFB/	CONWAY, HOMER & CHIN-CAPLAN PC	
2013-3511	05/03/2013 06/03/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	IOVATE - HYDROXYCUT, SMARTBURN, RAPIDSLIM & RAPID SLIM, ETC CAERS 2/13 TO PRESENT
2013-3512	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Goldy Singh Profound Medical Inc.	K120561
2013-3513	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103795 5356
2013-3514	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Griffin INNOVAQUARTZ INC	K050108
2013-3515	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K123420
2013-3516	05/06/2013 06/04/2013	FDA/OC/OES/DDM/	Susan Todd West-Ward Pharmaceutical Corp.	DOCKET 85D-0249
2013-3517	05/06/2013 06/04/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	HYDROQUINONE AS SKIN LIGHTENER
2013-3518	05/06/2013 06/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robert Brod BURG SIMPSON ET AL	DEPAKOTE, DEPAKOTE ER - LABELS
2013-3519	05/06/2013 06/04/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Doe J	INDIVIDUAL RECS
2013-3520	05/06/2013 06/04/2013	FDA/OF/CFSAN/OCD/EOS/	Doe J	AXE BODY SPRAY - INGREDIENTS
2013-3521	05/06/2013 06/04/2013	FDA/OF/CFSAN/OCD/EOS/	Jon Whelan Net Return, Inc.	AXE BODY SPRAY - INGREDIENTS

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2013-3522	05/06/2013 06/04/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	Katharine Mieszkowski The Center for Investigative Reporting	CORR RE ADDED SUGAR AND ADDED SUGAR NUTRITIONAL LABELING WITH SUGAR ASSOCIATION, CORN REFINERS ASSOCIATION, AMERICAN BAKERS ASSOCIATION ETC (05/02/2008 - 05/02/2013)
2013-3523	05/06/2013 06/04/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	LONZA, NH, MA - 483, EIR, CORR
2013-3524	05/06/2013 06/04/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Martin Robbins THE GUARDIAN	DR STANISLAW BURZYNSKI, HOUSTON, TX - INSPECTIONS, COMPLIANCE, ENFORCEMENT (01/01/1977 - 12/31/1986)
2013-3525	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B&H Consulting Services, Inc. B&H Consulting Services, Inc.	INDIVIDUAL CASE SAFETY REPORTS
2013-3526	05/06/2013 06/04/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	b burgess bernie burgess	SAMPLE SUMMARY, MEMO OF RESULTS OF ANALYSIS FACTS 808885
2013-3527	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Goldberg The Cancer Letter	TIVOZANIB - PRE-NDA MEETING DATE, ATTENDEES, AGENDA
2013-3528	05/06/2013 06/04/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Rachel Johnson FOI Services, Inc.	LONZA - EIR, 483, CORR
2013-3529	05/06/2013	FDA/OMPT/CDER/GRP/DIDP/	b. burgess	INTERNAL DSI CORR FROM DLW TO LKB 11/29/07

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	06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BURGESS, BERNIE	
2013-3530	05/06/2013 06/04/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	Mark Greenblatt SCRIPPS HOWARD NEWS SERVICE	IMPORT REFUSAL DATA (01/01/2008 - 05/02/2013)
2013-3531	05/06/2013 06/04/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	hollie telford hollie telford	DRUG AND HEALTH FOOD MANUFACTURERS REGISTERED WITH FDA
2013-3532	05/06/2013 06/04/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Shin Kang WELLS FARGO	GILEAD SCIENCES, FOSTER CITY - 483 (01/01/2012 - 05/02/2013)
2013-3533	05/06/2013 06/04/2013	FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	Slides, briefing materials for Peripheral & Central Nervous System Drugs AC Meeting 06/06/2001
2013-3534	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	Presentation given at NADDI National Conference
2013-3535	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NIDIA NOEL EZEM CANADA	HAORUI PHARMA CHEM INC - EIR, 483, CO RESP 7/13-16/11
2013-3536	05/06/2013 06/04/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	SANDRA M. BOGENRIEF, RN, LNC LOMMEN ABDO COLE KING STAGEBERG PA	CRONOBACTER INFECTION 2011
2013-3537	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARC RENDELL, MD ASNDI	BEOHRINGER INGELHEIM - LINAGLIPTIN APRVL, ADVISORY MTG

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3538	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	MEDLINE INDUSTRIES INC - TENDER WET WOUND DRESSING K991755
2013-3539	05/06/2013 06/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EMILY SETTLEMOIR Reliable Biopharmaceutical Corporation	SIGMA ALDRICH, BUCHS, SWITZERLAND - 483
2013-3540	05/06/2013 06/04/2013	FDA/OC/OES/DDM/	MERAV AKNIN MACCABI HEALTHCARE SERVICES	NERVOUS SYS DRUGS ADVISORY COMMITTEE MTG 1989
2013-3541	05/06/2013 06/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H. LEVINE ROPES & GRAY LLP	SYNERON MEDICAL LTD - BEAUTY ME K123845
2013-3542	05/06/2013 06/04/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HUNTER J. SHKOLNIK Napoli Bern Ripka Shkolnik, LLP	REPRODUCTIVE HEALTH A/C; PUBLIC CITIZENS REQUEST FOR A BAN OF THIRD GENERATION COMBINATION ORAL CONTRACEPTIVES CONTAINING DESOGESTREL
2013-3543	05/06/2013 06/04/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	BAILEY A. BLAIR HUFF POWELL & BAILEY	THE PERRY HOSPITAL, HOUSTON, TX - INSP 5/10
2013-3544	05/06/2013 06/04/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-3545	05/06/2013 06/04/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-3546	05/06/2013 06/04/2013	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	KATHERINE STRONG CARNER SIDLEY AUSTIN LLP	CORR SENT TO INSTITUTIONAL RVW BOARDS FORM 1/11 TO PRESENT
2013-3547	05/06/2013 06/04/2013	FDA/OF/CFSAN/OCD/EOS/	CATHERINE R. NEILSEN Keller and Heckman LLP	NO OBJECTION LTR FROM EUGENE COLEMAN 4/13/94
2013-3548	05/07/2013 06/05/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AGENSAN HEALTHCARE, FOND DU LAC, WI - EIRS, 483S CO RESP 11/07-13/12
2013-3549	05/07/2013	FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY	PEKING MEDICINE MANUFACTORY, TSUEN WAN, NEW

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	06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMSON REUTERS	TERRITORIES, HONG KONG - EIRS, 483S, CO RESP 04/30/12-05/04/12
2013-3550	05/07/2013 06/05/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	PHYSICIANS TOTAL CARE INC, TULSA, OK - EIRS,483S, CO RESP 01/24/12-02/24/12
2013-3551	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WYETH LEDERLE, CATANIA, ITALY - EIRS, 483S, CO RESP 07/09-20/12
2013-3552	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	PUGET SOUND BLOOD CENTER & PROGRAM, SEATTLE, WA - EIRS, 483S, CO RESP 01/14/13-02/15/13
2013-3553	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	INSTITUTO MASSONE SA, BUENOS AIRES, ARGENTINA - EIRS, 483, CO RESP 11/12, 11/13
2013-3554	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ORGANO SINTESIS S A DE CV, MEXICO - EIRS, 483S, CO RESP 10/12
2013-3555	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LABORATORIOS LIOMONT SA DE CV, MEXICO - EIRS, 483S, CO RESP 10/12
2013-3556	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGAN, IRVINE, CA - EIRS, 483S, CO RESP 08/26/93
2013-3557	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGAN, IRVINE, CA - EIRS, 483S, CO RESP 03/27/96
2013-3558	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLERGAN, IRVINE, CA - EIRS, 483S, CO RESP 04/27/98

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2013-3559	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ASADA MILLING CO LTD, GUNMA, JAPAN - EIRS, 483S, CO RESP 10/09-12/12
2013-3560	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANGIE BEYER AIRLIQUIDE	EZ-OX PLUS - K053117
2013-3561	05/07/2013 09/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ ORA/ ORA/ FDA/OC/OES/	CHRISTA C COTTRELL KIRKLAND & ELLIS LLP	PLASMA PROTEIN THERAPETICS ASSOCIATION (INTERNATIONAL PLASMA PRODUCTS INDUSTRY ASSOCIATION) - MFG OF PLASMA-DERRIVED PROTEIN THERAPIES ASSOCIATION (INTRAVENOUS IMMUNOGLOBULIN & ALBUMIN) ACTIONS TO IMPLEMENT GMP, FACILITY SHUT DOWNS, PROD QUARANTINES OR MFG CONSENT DECREES, ETC 1996 TO 2002, 1997 TO 2002
2013-3562	05/07/2013 06/05/2013	OC/OL/	MICHAEL MORISY MUCKROCK NEWS	CONGRESSIONAL COMMITTEES - RESP 1/08 TO PRESENT
2013-3563	05/07/2013 06/05/2013	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	Doe J	CMPLNT - APPLE JUICE
2013-3564	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	YVONNE M FLAHERTY LOCKRIDGE GRINDAL NAUEN PLLP	ST JUDE MEDICAL - RIATA, RIATA ST DEFIBRILLATOR LEADS 522 APPL NUMBER PS12011 LEAD EXTERNALIZATION AND ABRASION P950022
2013-3565	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT A COHEN DECHERT LLP	HOSPIRA INC, JAVELIN PHARMACEUTICALS INC - DYLOJECT CORR 10/07 TO PRESENT
2013-3566	05/07/2013 06/05/2013	FDA/OF/CFSAN/OCD/EOS/	MAE WU NATURAL RESOURCES DEFENSE COUNCIL	TOTAL DIET STUDY INDUSTRIAL CHEMICAL RESIDUE MONITORING 2004 TO 2012
2013-3567	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	TEVA PHARMACEUTICALS USA - PALONOSETRON HCL ANDA 202-224 CORR
2013-3568	05/07/2013 06/05/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Doe J	CHURCH & DWIGHT COMPANY INC - ARM & HAMMER PEROXIDE CARE TOOTHPASTE CMPLNTS LAST 5 YRS

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2013-3569	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	GREGORY H LEVINE ROPES & GRAY LLP	SYNERON MEDICAL LTD - ME HAIR2GO K121598
2013-3570	05/07/2013 06/05/2013	ORA/ ORA/	Stuart Warner YALE-NEW HAVEN HOSPITAL	MED PREP PHARMACY INC, TINTON FALLS, NJ - TESTING INFORMATION AND FINDINGS
2013-3571	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW L CANTWELL PICOLIFE TECHNOLOGIES LLC	TANDEM - T:SLIM K111210; MEDTRONIC - MINIMED K990801; NIPRO - AMIGO K071613
2013-3572	05/07/2013 06/05/2013	ORA/ ORA/	Stuart Warner YALE-NEW HAVEN HOSPITAL	CENTRAL ADMIXTURE PHARMACY SERVICES, INC, WALLINGFORD, CT - PLAN OF CORRECTION (02/19/2013 - 05/07/2013)
2013-3573	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 202224
2013-3574	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAvid Knasack Orthocon, Inc	K111538
2013-3575	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Institute Ctr for Med Media	AMBIEN CR, LIPITOR, LOPRESSOR, ETC - APPROVAL RECS FOR NDA SUPPLEMENTS
2013-3576	05/07/2013 06/05/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shirley Duggan Smiths Medical ASD, Inc.	SMITHS MEDICAL ASD, ROCKLAND, MA - EIR (01/18/2011 - 01/28/2011)
2013-3577	05/07/2013 06/05/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Sylvester Williams III WuXi AppTec Inc.	MUSCULOSKELETAL TRANSPLANT FOUNDATION, EDISON, NJ - EIR, 483 (09/17/2012 - 12/30/2012)
2013-3578	05/07/2013 06/05/2013	FDA/OC/OES/DDM/	Rachel Johnson FOI Services, Inc.	Script and Video for Xyrem Prescription and Distribution Process submitted to FDA by Orphan Medical on 05/30/2001 for the FDAsPeripheral and Central Nervous System Drugs Advisory Committee meeting on 06/06/2001
2013-3579	05/07/2013 06/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess bernie burgess	Internal FDA correspondence or letter received by DSI on 9/27/07
2013-3580	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lois Chandler CARDIUM THERAPEUTICS	K072113
2013-3581	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	K980482, K972651, K955349 ETC

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2013-3582	05/07/2013 06/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess bernie burgess	ORIGINAL SIGNED EIR FOR 94092
2013-3583	05/07/2013 06/05/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Kathi Prudente Prudente, Kathi	COMFREY IN BURT'S LIP BALM (08/23/2012 - 05/06/2013)
2013-3584	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lois Chandler CARDIUM THERAPEUTICS	K083440
2013-3585	05/07/2013 06/05/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Francisco Polonio Laboratorios Lesvi, S.L.	ALGORITHM PHARMA, CANADA - ALL INSPECTION RECS 01/01/2011 TO PRESENT
2013-3586	05/07/2013 06/05/2013	ORA/OCI/ ORA/OCI/	Kathleen Martin-Weis MERCK & CO., INC.	COUNTERFEIT CRIVIAN - LAB ANALYSIS
2013-3587	05/07/2013 06/05/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Julie Butler Olive Oil Times	AVB-2080130-0/1/1 OLIVOS GIDA YAG TARIM SAN. ITH.IHR. VE TIC A.S.
2013-3588	05/07/2013 06/05/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Brendan Ryan WARNER CHILCOTT	BAXTER HEALTHCARE, CLEVELAND, MS - EIR (01/01/2010 - 12/31/2010)
2013-3589	05/07/2013 06/05/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Lena Gomez Keller and Heckman, LLP	FORMOR INC, CONWAY, ARK - 483, RESPONSE TO WARNING LETTER
2013-3590	05/07/2013 06/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Manfred Abel Greiner Bio-One	BK070029 SUMMARY
2013-3591	05/07/2013 06/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JULIA G YOUNG STRICK LAW FIRM PLLC	DAVOL INC - MESH COMPOSIX KUGEL PATCH RECS
2013-3592	05/07/2013 06/05/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	FOREIGN & DOMESTIC DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - 483S 3/1-31/13

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2013-3593	05/07/2013 06/05/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	MIKE RUSSELL DELAVAL MANUFACTURING	WEST AGRO INC, HAMILTON, NY - EIR, 483S 2/27/12-3/7/12
2013-3594	05/07/2013 06/05/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	LAUREN HANSON WBKO TV	HILLS NUTRITION, BOWLING GREEN, NY - SALMONELLA INVESTIGATION 1/13
2013-3595	05/07/2013 06/05/2013	FDA/OO/OFBA/OAGS/	KIM, MARLENE	BIG ENTERPRISES INC, WALDORF, MD - CONTRACT OR GRANT APPLS FUNDED BY HHS AND FDA
2013-3596	05/07/2013 06/05/2013	FDA/OC/OES/DFOI/	GUMPERT, DAVID .	DELETIONS TO OCC RESPONSE
2013-3597	05/08/2013 06/06/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (04/29/2013 - 05/03/2013)
2013-3598	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	Deb Winkler Putney, Inc.	NOROCARP - APPROVAL LETTER
2013-3599	05/08/2013 06/06/2013	ORA/OE/ ORA/OE/	Brent Ardaugh Framingham Heart Study	FDA ENFORCEMENT REPORT - RECALL NOTICE OF MICROVASIVE UROLOGY PRODUCTS PROTEGEN COLLAGEN IMPREGNATED SLING AND VESICA SLING KITS WITH PROTEGEN 3/17/99
2013-3600	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shelf life of Actigall (Ursodiol 300mg capsule) Daewoong America Inc.	ACTIGALL - SHELF LIFE
2013-3601	05/08/2013 06/06/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Lim Meng How Crystal Aesthetics	BACTOLAC PHARMACEUTICAL, HAUPPAUGE, NY - CGMP CERTIFICATION, LICENSE
2013-3602	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Trupti Shah TAKEDA PHARMACEUTICALS NA INC	CASE REPORTS
2013-3603	05/08/2013	FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber	NDA 20553, NDA 20622

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	06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dartmouth Institute Ctr for Med Media	
2013-3604	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Institute Ctr for Med Media	COPAXONE, CELEBREX, NEXIUM ETC - APPROVAL RECS FOR SUPPLEMENTS
2013-3605	05/08/2013 06/06/2013	OC/OL/	Jake Sherman POLITICO	COMM WITH REP ERIC CANTOR RE STAR SCIENTIFIC, JOHNNIE R WILLIAMS
2013-3606	05/08/2013 06/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ratinder Brar St. Jude Medical	K970943 - SUMMARY
2013-3607	05/08/2013 06/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ratinder Brar St. Jude Medical	K981820 - SUMMARY
2013-3608	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 78702 APPROVAL LETTER
2013-3609	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeff Schaffer Bloomington Drug	NDA 009925
2013-3610	05/08/2013 06/06/2013	ORA/OE/ ORA/OE/	Justin Fregia ValueScope, Inc.	FDA ENFORCEMENT WEEKLY REPORTS 1991-2003
2013-3611	05/08/2013 06/06/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3238
2013-3612	05/08/2013 06/06/2013	FDA/OF/CFSAN/OCD/EOS/	HELLEN A. OKETCH, Ph.D. US PHARMACOPEIAL CONVENTION	CALCIUM MAGNESIUM PHYTATE - CAERS 2/05; 4/13
2013-3613	05/08/2013 06/06/2013	FDA/OF/CFSAN/OCD/EOS/	HELLEN A. OKETCH, Ph.D. US PHARMACOPEIAL CONVENTION	METHYLCOBALAMIN - CAERS 1/05; 4/13
2013-3614	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATY MORTON TOPICA PHARMACEUTICALS INC	YONEZAWA HAMARI CHEMICALS CO LTD, YAMAGATA, JAPAN - EIR 1/12 TO PRESENT

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-3615	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LIBBE ENGLANDER, Ph.D PHARM3R	8403630-5; 8458718-X; 6643895-3 - MEDWATCH RPT
2013-3616	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMI DALBERG INDENA USA INC	SICOR DE MEXICO SA DE CV, LERME, MEXICO - EIR 11/25/09
2013-3617	05/08/2013 06/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMI DALBERG INDENA USA INC	SICOR ITALY, SANTHIA, ITALY - EIR 12/16/10
2013-3618	05/08/2013 06/06/2013	FDA/OF/CFSAN/OCD/EOS/	CYNTHIA M. BARBER PBM Nutritionals LLC	MEAD JOHNSON NUTRITION - INFANT FORMULA
2013-3619	05/08/2013 06/06/2013	FDA/OF/CFSAN/OCD/EOS/	CYNTHIA M. BARBER PBM PRODUCTS LLC	ABBOTT LABS - INFANT FORMULA
2013-3620	05/08/2013 06/06/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	DAVID C. WEBER BEHREND & ERNSBERGER PC	MUTUAL PHARMACEUTICAL CO - PREDNISONE EIR 1993 TO PRESENT
2013-3621	05/08/2013 06/06/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	PAUL B. CALLAHAN CHARLES RIVER LABS	WIL RESEARCH. ASHLAND OH - 483 3/12
2013-3622	05/08/2013 06/06/2013	FDA/OF/CFSAN/OCD/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 164646 4/23/13
2013-3623	05/08/2013 06/06/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RICHARD A. WRIGHT, Esq. CORY WATSON ET AL	OMONTYS - EIRS, 483S, WARNING LTRS, ETC
2013-3624	05/08/2013 06/06/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/	AVDEEF, STEPHEN	CORR BETWEEN SAMS CLUB & CDC REGARDING 2006 BURKHOLDERIA CEPACIA RECALL

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		ORA/		
2013-3625	05/08/2013 06/06/2013	FDA/OC/OES/DFOI/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	2003-2337; 4834; 11319 ETC
2013-3626	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary J. Syring Quality & Regulatory Associates, LLC	K860219
2013-3627	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachelle Lyon Lyon, Rachelle	XTANDI, ZYTIGA - AERS
2013-3628	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim waldron Univeristy of Iowa Hospital & Clinics	K852612
2013-3629	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Griffin INNOVAQUARTZ INC	K110685
2013-3630	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Albright Lexicon Pharmaceuticals, Inc.	NDA 020386
2013-3631	05/09/2013 06/07/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Samuel Coe, Assistant Corporate Attorney Newly Weds Foods, Inc.	NEWLY WED FOODS INC, YORKVILLE, IL - ALL INSPECTION RECS (01/01/2013 - 05/08/2013)
2013-3632	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Candice Durrence Optimer Pharmaceuticals, Inc.	DIFICID - AERS
2013-3633	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Mevs Martin Clearwater & Bell, LLP	Clinical trials of chemotherapy by Super-Selective Intraarterial Intracranial Infusion of Temozolomide (Temodar)

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2013-3634	05/09/2013 06/07/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Vicki E. Babbert Ice Miller, LLP	Investigation and Testing of Instant Milk Protein Concentrate 80% (IMPC-80) at Plainview Milk Products Cooperative, Plainview, Minnesota
2013-3635	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ivan King Qi Oncology LLC	NDA 18154
2013-3636	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sasha Gelfand ControlRad Systems Ltd	K031597
2013-3637	05/09/2013 06/07/2013	FDA/OF/CFSAN/OCD/EOS/	MARY ANN COMSTOCK UPS SUPPLY CHAIIN SOLUTIONS	UPS SUPPLY CHAIN SOLUTIONS INC, UNITED PARCEL SERVICE INC, UNITED PARCEL SERIVCE OF AMERICA INC, ETC LISTED AS US AGENT UNDER THE BIOTERRORISM ACT OF 2002 AND/OR FOOD SAFETY MODERNIZATION ACT
2013-3638	05/09/2013 06/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA S DELAND KITCH DRUTCHAS ET AL	HI HEALTHINNOVATIONS - HEARING TESTING, HEARING AIDS FITTING, SALES, ETC 3/2912
2013-3639	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOE E MATTHEWS JR OLIVER MANER LLP	VFEND, VYTORIN, ZOCOR, ETC - AERS
2013-3640	05/09/2013 06/07/2013	ORA/ ORA/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WILLIAMS, NATHANIA M	CMPLNT 131379
2013-3641	05/09/2013 06/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HELTON, SHARLA	ALLERGAN - BOTOX, BOTOX COSMETIC AERS
2013-3642	05/09/2013 06/07/2013	FDA/OGROP/ORAPAF-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	DYNAVAX - EIR, 483, CO RESP, ETC 2012
2013-3643	05/09/2013 06/07/2013	FDA/OGROP/ORAPAF-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	JANSSEN ALZHEIMER IMMUNOTHERAPY - EIR, 483S, CO RESP, ETC 2010 TO 2012
2013-3644	05/09/2013 06/07/2013	FDA/OGROP/ORAPAF-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	TALON THERAPEUTICS (HANA BIOSCIENCE) - EIR, 483, CO RESP, ETC 2011-2012

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2013-3645	05/09/2013 06/07/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	OXIGENE - EIR, 483, CO RESP, ETC 2011-2012
2013-3646	05/09/2013 06/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	BRISTOL MYERS SQUIBB - EIR, 483, CO RESP, ETC 2011-2012
2013-3647	05/09/2013 06/07/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	JANSSEN/JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT - EIR, 483S, CO RESP, ETC 2008-2012
2013-3648	05/09/2013 06/07/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	REGENERON, TARRYTOWN, NY - EIR, 483, CO RESP, ETC 2011-2012
2013-3649	05/09/2013 06/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	BIOGEN-IDEA, BOSTON, MA - EIR, 483, CO RESP, ETC 2010-2012
2013-3650	05/09/2013 06/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	LIZ WOOL QD-QUALITY AND TRAINING SOLUTIONS	PFIZER, GROTON, CT - EIR, 483, CO RESP, ETC 2008-2012
2013-3651	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K062048
2013-3652	05/10/2013 06/10/2013	FDA/OC/OES/DFOI/	Bob Mitchell - Req1 Executive Leadership Services, LLC	HHSF223200830014I
2013-3653	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	PIP SALINE IMPLANTS - LETTER TO DOCTORS
2013-3654	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Candice Durrence Optimer Pharmaceuticals, Inc.	DIFICID - APPROVAL RECS
2013-3655	05/10/2013 06/10/2013	FDA/OC/OES/DFOI/	Bob Mitchell Req2 Executive Leadership Services, LLC	HHSF223200830014I - PROPOSAL RECS
2013-3656	05/10/2013 06/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Emily Settlemoir Reliable Biopharmaceutical Corporation	QUIMICA SINTETICA SA, SPAIN - EIR OR 483

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2013-3657	05/10/2013 06/10/2013	FDA/OC/OES/DFOI/	Andrew D. Cardon NATIONAL ASSOCIATION FOR BIOMEDICAL RESEARCH	FOIA REQUEST LOG 05/09/2012 - 05/09/2013
2013-3658	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Diane Horwitz - Medskin MANDELL HORWITZ CONSULTANTS LLC	K072113
2013-3659	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Megan Burns DEPUY ORTHOPAEDICS INC	K111863, K121640, K122053
2013-3660	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Chitemerere Stratdigm	ORANGE BOOK DATA (01/02/2001 - 12/12/2002)
2013-3661	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 200153
2013-3662	05/10/2013 06/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natalie Morrison BIOPHARM INSIGHT	ASTRAZENECA, MACCLESFIELD, UK - INSPECTION RECS, WARNING LETTERS
2013-3663	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Salcedo Jonathan Paul Eyewear	FGZ INTERNATIONAL, INC, DIOPTICS MEDICAL PRODUCTS,LIVE EYEWEAR, INC - REGISTRATION RECS
2013-3664	05/10/2013 06/10/2013	FDA/OF/CFSAN/OCD/EOS/	Luz Agana San Francisco Asthma Task Force	21 CFR 178.1010 - STUDY INFORMATION
2013-3665	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGELHEIN PHARMA GMBH & CO KG, INGELHEIM AM RHEIN, GERMANY - 483 MOST RECENT
2013-3666	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER INGLHEIM PHARMA GMBH & CO KG, BIBERACH AN DER RISS, GERMANY - 483 MOST RECENT

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2013-3667	05/10/2013 06/10/2013	FDA/OF/CFSAN/OCD/EOS/	DATZ, JANIS	AVON PRODUCTS INC - WARNING LTR 10/5/12
2013-3668	05/10/2013 06/10/2013	FDA/OF/CFSAN/OCD/EOS/	DATZ, JANIS	LANCOME USA - WARNING LTR 9/7/12
2013-3669	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	TESS M SCHOENTHAL UNIV OF CALIFORNIA BERKELEY	DKT 1978N-1665
2013-3670	05/10/2013 06/10/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN S BAKER LIGHTFOOT FRANKLIN & WHITE LLC	TESTOPEL - RECS
2013-3671	05/10/2013 06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDI L PRUITT UNIV OF TEXAS SOUTHWEST MEDICAL CTR	LIST OF MAMMOGRAPHY FACILITIES, TX 1990 TO 2013
2013-3672	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLIE LITTON UNEMED	LIST OF ANNUAL HISTORICAL RECS REGARDING THE NUMBER OF ANTIBIOTIC DRUG APPL & THE NUMBER OF ANTIBIOTIC DRUG APRVL IN HUMANS 1960 TO PRESENT
2013-3673	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CANDICE CHARTAIN MCINTOSH LAW FIRM PC	LYPRON NDA 20-517; SYNAREL NDA 19-886; MEGCE NDA 20-264 - PI, MEDICATION GUIDES
2013-3674	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WENDY LOU JONES ROYAL KNIGHT INC	BAXTER HEALTHCARE CORP (BAXTER HYLAND), GLENDALE, CA - CEPROTEIN (PROTEIN-C) CONCENTRATE RECS
2013-3675	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 4/1- 30/13
2013-3676	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NICK BUDNICK OREGONIAN	PATRICK WITHAM, PATRICK H WITHAM, PARAGON BIOTECH, ETC - NDAS, COMMENTS, RVWS, ETC

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2013-3677	05/10/2013 06/10/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	GILBERT R WEINER ADVANCEDPHARMA	CETERO RESEARCH - EIRS, CLASSIFICATION LTR
2013-3678	05/10/2013 06/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LATESHA R BAKER HINSHAW & CULBERTSON LLP	VAERS 48310, 480899, 485907
2013-3679	05/10/2013 06/10/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICALS, BIOLOGICS & MEDICAL DVC MFG & CLNCL TRIAL FACILITIES BOTH INSIDE & OUTSIDE THE USA - 483S 4/1-30/13
2013-3680	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	GAYLEC SHULTZ KIRKLAND & ELLIS LLP	ODAC A/C TR MIN 06/17/1993
2013-3681	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CYNTHIA MEYER KLEINFELD, KAPLAN & BECKER	DKT 2002P-0435
2013-3682	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1977N-0094
2013-3683	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	JOYCE MUTCHERSON-RIDLEY WOLTERS KLUWER	DKT FDA-2011-S-0932, FDA-2012-S-1144, ETC.
2013-3684	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2013-P-0283
2013-3685	05/10/2013 06/10/2013		FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3686	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3687	05/10/2013 06/10/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Matthew Welsch ThermaSolutions, Inc.	EIGHT MEDICAL CORPORATION, HEI CORPORATION - INSPECTION RECS (09/03/2012 - 05/07/2013)
2013-3688	05/10/2013 06/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 50718 S 020, 029 DOXIL
2013-3689	05/10/2013 06/10/2013	FDA/OF/CFSAN/OCDE/EOS/	Rachel Johnson FOI Services, Inc.	CORR WITH CONSOLIDATED FLAVOR CORP
2013-3690	05/10/2013	FDA/OC/OES/DDM/	CHRIS CELESTE	OTC VOL. 080173, 080174, ETC.

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	06/10/2013		EAS CONSULTING GROUP LLC	
2013-3691	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058
2013-3692	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	OTC VOL. 080010, 080057, ETC.
2013-3693	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CHRIS CELESTE EAS Consulting Group, LLC	OTC VOL. 080064, 080085, ETC.
2013-3694	05/10/2013 06/10/2013	FDA/OC/OES/DDM/	CHRIS TURNER CITIZENS FOR HEALTH	DKT FDA-2010-P-0491, FDA-2012-P-0904, ETC.
2013-3695	05/13/2013 06/11/2013	FDA/OF/CFSAN/OCD/EOS/	CYNTHIA B LIEBERMAN Keller and Heckman LLP	DUPONT DOW ELASTOMERS LLC - FCN 368; MITSUI CHEMICALS INC - FCN 806, FCN 917, FCN 1120 CHEMISTRY, TOXICOLOGY, ENVIRONMENTAL RVW MEMOS
2013-3696	05/13/2013 06/11/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC INC	SHAMPOOS AND PREPARATIONS FOR USE ON THE HAIR ENTRY #EHP-00771985-8 - RECS
2013-3697	05/13/2013 09/03/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	FDA, HHS ASSISTANT SECRETARY FOR PLANNING AND EVALUATION - FRONT-OF-PACKAGE LBLG SYS RECS FY2014
2013-3698	05/13/2013 09/03/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	BOBBY SCHOCHET OLSSON FRANK WEEDA TERMAN MATZ PC	GROCERY MFRS ASSN - FRONT-OF-PACKAGING (FOP) LBLG SYS
2013-3699	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ACTIENT PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3700	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	AUXILIUM PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3701	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	INTUITIVE SURGICAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3702	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	THORATEC CORP - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3703	05/13/2013 06/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	ABAXIS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3704	05/13/2013 06/11/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	MEDIVATION INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3705	05/13/2013	FDA/OGROP/ORA/CE-FO/NWJ-	ANDREW HACK MD PHD	NPS PHARMACEUTICALS INC - EIRS, 483S, UNTITLED

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	06/11/2013	DO/NWJ-CB/	MILLENNIUM MANAGEMENT LLC	LTRS, ETC 1/12 TO PRESENT
2013-3706	05/13/2013 06/11/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	WRIGHT MEDICAL GROUP INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3707	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	AERS 8237200
2013-3708	05/13/2013 06/11/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	RESMED INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3709	05/13/2013 06/11/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	HEARTWARE INTERNATIONAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3710	05/13/2013 06/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Angelina Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SHELDON FREEDMAN, MD, LAS VEGAS, NV - EIR, 483 06/01/2012-07/25/2012
2013-3711	05/13/2013 06/11/2013	FDA/OMPT/CTP/OD/	Doe J	TOP CIGARETTE TOBACCO, BUGLER TOBACCO - INGREDIENTS
2013-3712	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Loxitane NDA Watson Laboratories, Inc.	NDA 17525
2013-3713	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chantal Frontczak Hemodia SAS	K925160, K954465, K951843 ETC
2013-3714	05/13/2013 06/11/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	BIOMARIN PHARMACEUTICAL INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3715	05/13/2013 06/11/2013	CVM/OCD/	Blaine Baker, Regulatory Manager Virbac AH, Inc	NADA 140869
2013-3716	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/	Michael Moss THE NEW YORK TIMES	FOOD AND BEVERAGE FOIA REQUESTS (05/10/2011 - 05/10/2013)
2013-3717	05/13/2013 06/11/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS INC - EIRS, 483S, UNTITLED LTRS, ETC 1/12 TO PRESENT
2013-3718	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/ ORA/ ORA/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE, SYLMAR, CA - INSPECTION RECS, CORR

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		FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		
2013-3719	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	CDER/DSI GCP C/R/S 1840
2013-3720	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	EPOGEN - APPROVAL RECS
2013-3721	05/13/2013 06/11/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess bernie burgess	EMAILD DATED 9/26/2011 TO OSI RE COMPLAINT TO COMMISSIONER
2013-3722	05/13/2013 06/11/2013	ORA/ ORA/	Tony Collins-Kwong ALLINA HEALTH SYSTEM	PHARMERICA - 483 (01/01/2011 - 05/10/2013)
2013-3723	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brian Overstreet AdverseEvents, Inc.	AERS 8002028, 7917378, 7064380, ETC
2013-3724	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b burgess bernie burgess	CORR FROM BEHR ON 2/14/11 TO OSI RE DISPUTE
2013-3725	05/13/2013 06/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BIOPHARM INSIGHT	DRUGS FOR WHICH BT DESIGNATION APPLICATIONS WERE FILED, APPROVED, NAMES OF SPONSORS (07/09/2012 - 04/30/2013)
2013-3726	05/13/2013 06/11/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-	Eric Puente Puente, Eric	HEB TOMATO SAMPLES

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		DO/DAL-CB/		
2013-3727	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K061982
2013-3728	05/13/2013 06/13/2013	FDA/OC/OES/DFOI/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITY INSPECTIONS - 483 (10/01/2011 - 12/31/2012)
2013-3729	05/13/2013 06/11/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Collin L. Freer Berman Fink Van Horn P.C.	SEED BIOTECH, DALLAS, TX - FILINGS, REGISTRATION, ETC
2013-3730	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jorge Hernn Ramrez Universidad Icesi	RNS60 - APPROVAL FOR STUDIES, IND
2013-3731	05/13/2013 06/11/2013	ORA/ ORA/ FDA/OF/CFSAN/OCD/EOS/ ORA/OCI/ ORA/OCI/	Cheryl Cheryl	ZI XIU TANG BEE POLLEN - FINDINGS OF SIBUTRAMINE, WARNING LETTER (09/01/2012 - 06/01/2013)
2013-3732	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jacques Jentel DuPage Medical Group / Jacques Jentel, M.D.	ULTRAM, ULTRAM ER, TRAMADOL, ETC - AERS
2013-3733	05/13/2013 06/11/2013	FDA/OC/OES/DDM/	Advisory Committee Meetings Orthopaedic and Rehab Devices Peter Boone	ORTHOPAEDIC AND REHABILITATION DEVICES - TRANSCRIPTS 7/22/1994-7/23/1994
2013-3734	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-1123, 1571, 1729 ETC
2013-3735	05/13/2013 06/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	PONATINIB (ICLUSIG) AER 1/13 TO PRESENT
2013-3736	05/13/2013	FDA/OMPT/CDER/ERP/DIDP/	ELLIOT FAVUS	ADCETRIS (BRENTUXIMAB VEDOTIN) AER 1/13 TO PRESENT

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	06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	FAVUS INSTITUTIONAL RESEARCH LLC	
2013-3737	05/13/2013 06/11/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRIAN M. OVERSTREET ADVERSE EVENTS	HYDROXYUREA AER9/12 TO PRESENT
2013-3738	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/	THORNHILL 322084, CHRIS	NUTRITIONAL CALORIE VALUE
2013-3739	05/13/2013 06/11/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GOINS 302385, MICHAEL	BENTY; REMRON; VISTONL ETC - AER
2013-3740	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PATRICIA L. REGENYE Celgene Corporation	MARGRIT SIMON, BERLIN, GERMANY - 483 10/09 TO PRESENT
2013-3741	05/13/2013 06/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WATTS, LEWIS	PUBLIC WORKSHOP - LBLG 4/29-30/13
2013-3742	05/13/2013 06/11/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	HAROLD G. FURLOW HAROLD G FURLOW ATTORNEY AT LAW	ZIMUSSU0221 7/15/05; ZIMUSSRO37 9/8/05 - ENTRY DOCS

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2013-3743	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIUAL RECS
2013-3744	05/13/2013 06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BETH ZIEMBA CELL THERAPEUTICS INC	8681891, 8917306, 9023966 ETC - MEDWATCH
2013-3745	05/13/2013 06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PHARMACOVIGILANCE RVW 12/15/11 - UNREDACTED PAGE 33
2013-3746	05/13/2013 06/17/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	ERIN E. SEDER VENABLE LLP	ALL DIETARY SUPPLEMENT & OTC DRUG COMPANIES TO DISCUSS AER - 483 6/09 TO PRESENT; NUMBER OF AER 2008 TO PRESENT
2013-3747	05/13/2013 06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	LUCINDA J. TODD HILL ROM	LINET SPOL SRO - 483 10/29/12 TO 11/2/12
2013-3748	05/13/2013 06/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WENDY JO ROGERS CORSON & JOHNSON LAW FIRM	AMIODARONE - NDA; PEACE HEALTH RIVER BEND HOSPITAL, EUGENE, OREGON 2008 TO 2013; FAERS RPT
2013-3749	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG - (05/06/2013 - 05/10/2013)
2013-3750	05/14/2013 06/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rebecca Britton Oregon Health & Science University Hospitals and Clinics	BERIPLEX P/N - TRIAL RECS
2013-3751	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Erik van den Akker Erik van den Akker	NCT00046020 - STUDY DATA
2013-3752	05/14/2013 06/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	HOSPITAL UNIVERSITARIO, DR JOSE E GONZALEZ, MONTERREY, MEXICO - INSPECTION RECS (05/02/2007 - 05/02/2013)

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		FDA/OMPT/CDRH/OCER/DFOI/		
2013-3753	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ramanareddy Posam Self	PREDNISONE - CLINICAL TRIALS, AERS
2013-3754	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Bush Vertex Pharmaceuticals, Incorporated	AESICA PHARMACEUTICALS LIMITED - QAP PROFILE
2013-3755	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Bush Vertex Pharmaceuticals, Incorporated	AESICA PHARMACEUTICALS GMBH - QAP
2013-3756	05/14/2013 06/12/2013	FDA/OGROP/ORACE-FO/CIN- DO/CIN-CB/	Brendan Ryan WARNER CHILCOTT	EMERALD PERFORMANCE MATERIALS - EIR (05/13/2010 - 05/13/2013)
2013-3757	05/14/2013 06/12/2013	FDA/OMPT/OSMP/OOPD/	Scott Wilkin UBS AG	PROCYSBI - ORPHAN DRUG DESIGNATION
2013-3758	05/14/2013 06/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Molly Juhlin OREGON HEALTH SCIENCES UNIVERSITY	ITRACONAZOLE WITH SAQUINAVIR - TRIAL RECS
2013-3759	05/14/2013 06/12/2013	FDA/OGROP/ORACE-FO/ATL- DO/ATL-CB/	Amber Baker BioNetwork	GAIA HERBS, BREVARD, NC - 483 (05/01/2009 - 05/13/2013)
2013-3760	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/15-19/13
2013-3761	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/22-26/13
2013-3762	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/15-19/13
2013-3763	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/22-26/13
2013-3764	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	FOI DAILY LOG 4/15-19/13

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			BUSINESS	
2013-3765	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/22-26/13
2013-3766	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/15-19/13
2013-3767	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/22-26/13
2013-3768	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/15-19/13
2013-3769	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 4/22-26/13
2013-3770	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 4/15-19/13
2013-3771	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 4/22-26/13
2013-3772	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/15-19/13
2013-3773	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/22-26/13
2013-3774	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 4/15-19/13
2013-3775	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 4/22-26/13
2013-3776	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/15-19/13
2013-3777	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/22-26/13
2013-3778	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/15-19/13
2013-3779	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/22-26/13

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2013-3780	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 4/15-19/13
2013-3781	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 4/22-26/13
2013-3782	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/15-19/13
2013-3783	05/14/2013 06/12/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/22-26/13
2013-3784	05/14/2013 06/12/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	STEVEN C GLICKMAN GLICKMAN & GLICKMAN LAW OFCS	BOTULISM INVESTIGATION - INDIVIDUAL RECS
2013-3785	05/14/2013 06/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER ESQ WILSON SONSINI ET AL	BANNER - ANDA 200-899; ROXANE - ANDA 202-204; SANDOZ - ANDA 202-660 TENTATIVE APRVL LTRS
2013-3786	05/14/2013 06/12/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SHELLY S JOCK RALPH C JONES LAW OFCS	OLYMPUS - SURGMASTER ELECTROSURGICAL UNIT (UES-40) CLASS 2 RECALL
2013-3787	05/14/2013 06/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KIMBERLY A GRABBE MAGLIO CHRISTOPHER & TOALE LAW FIRM	INDIVIDUAL RECS
2013-3788	05/14/2013 06/12/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Doe J	CMPLNT
2013-3789	05/14/2013 06/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	AVERY DENNISON CORP - K113836
2013-3790	05/14/2013 06/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHINNY, C WENDY	TEVA PHARMACEUTICALS USA - PALONOSETRON HCL ANDA 202-224 CORR
2013-3791	05/14/2013	FDA/OC/OES/DDM/	FATIMA ASLAM	DKT FDA-1985-G-0511

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	06/12/2013		Keller and Heckman LLP	
2013-3792	05/14/2013 06/12/2013	FDA/OC/OES/DDM/	FATIMA ASLAM Keller and Heckman LLP	DKT FDA-1985-G-0511
2013-3793	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5611
2013-3794	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-5589
2013-3795	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-4763
2013-3796	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8712
2013-3797	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2009-3073
2013-3798	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8717
2013-3799	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-3064
2013-3800	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8021
2013-3801	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-1082
2013-3802	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7578
2013-3803	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7708
2013-3804	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7433
2013-3805	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8750
2013-3806	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-8581
2013-3807	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7281

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2013-3808	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-6988
2013-3809	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7022
2013-3810	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9523
2013-3811	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-7008
2013-3812	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7429
2013-3813	05/15/2013 06/13/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	Scott A. Hodes Scott A. Hodes, Attorney at Law	GILEAD SCIENCES, FOSTER CITY - 483 (01/01/2013 - 05/15/2013)
2013-3814	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Gonzales AMGEN INC.	MUSTAFA NEVZAT PHARMACEUTICALS, TURKEY - EIR (01/03/2012 - 05/14/2013)
2013-3815	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christine Nichols Boston Biomedical Associates	K113313
2013-3816	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Hodes Scott A. Hodes, Attorney at Law	ICLUSIG - AERS
2013-3817	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K091515
2013-3818	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	KATHLEEN BERNHARD GEORGIA INSTITUTE OF TECHNOLOGY	K913882, K981851, K974653 - SUMMARY
2013-3819	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Ellis Andrew Ellis	VIDEX, VIDEX EC - AERS (01/01/1990 - 12/31/2006)
2013-3820	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Art Rankis Art Rankis	K082217

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2013-3821	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE MEDICAL - INSPECTION RECS RE LEAD PRUDUCTS
2013-3822	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nathan Bryson CYNAPSUS THERAPEUTICS INC.	APOKYN - POSTMARKETING COMMITMENTS, PROTOCOLS, FINAL REPORTS
2013-3823	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K061871
2013-3824	05/15/2013 06/13/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	SAMPLE 783279 - TEST RESULTS
2013-3825	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Zarembinski BioTime, Inc.	K112568, K022995, K945835 ETC
2013-3826	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Calvin Lin UOC USA INC.	K123339
2013-3827	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kate Gitter Plexus Corp.	PLEXUS MANUFACTURING, PENANG, MALYSIA - EIR JAN 2009
2013-3828	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Holm Uhlig UNIVERSITY OF OXFORD	ZAVESCA - ISR 5599512, 5587626, 5681080 ETC
2013-3829	05/15/2013 06/13/2013	OC/OL/	Susanna Monseau, Associate Professor, TCNJ Susanna Monseau	RESPONSES TO REP ISSA RE MCNEIL CONSENT DECREE
2013-3830	05/15/2013 06/13/2013	FDA/OC/OES/DDM/	ELENA HOWELL HOGAN LOVELLS LLP	DKT FDA-2006-P-0010

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2013-3831	05/15/2013 06/13/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	STEVE D. MATTERI CONTEMPORARY PRODUCTS INC	VETERINARY SERVICE INC, FRESNO, CA - EIR 3/23/10
2013-3832	05/15/2013 06/13/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	STEVE D. MATTERI CONTEMPORARY PRODUCTS INC	VETERINARY SERVICE INC, MODESTO, CA - EIR 6/4/10
2013-3833	05/15/2013 06/13/2013	FDA/OC/OES/DDM/	AMY WILLMAN XLEAR	DCK 80N-0042
2013-3834	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANNA McCUTCHEN RYMED TECHNOLOGIES INC	BIOPATCH K003229
2013-3835	05/15/2013 06/13/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	THOMAS P. RIEDERER PE TRUE VISION SYSTEMS INC	TRUE VISION SYS, GOLETA, CA - EIR 3/11-12/13
2013-3836	05/15/2013 06/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HILL, CYNTHIA	TRADJENTA - RECS
2013-3837	05/15/2013 06/13/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	COVANCE INC - 483, EIR, UNTITLED LTRS 1/12 TO PRESENT
2013-3838	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH A. BATTS ULMER BERNE LLP	ROZINN ELECTRONICS INC - NETLINK K020213
2013-3839	05/15/2013 06/13/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	LOPER, MATTHEW	ALLO SOURCE - WARNING LTR 2010 TO PRESENT
2013-3840	05/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	CARMELA R. WITMER	THOMAS MEDICAL PRODUCTS INC, MALVERN, PA - BARD CHANNEL FX TRANSSEPTAL SHEATH KIT - ALL

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	06/13/2013		ATLEE HALL BROOKHART LLP	DOCUMENTS
2013-3841	05/15/2013 06/13/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	STUTE, HANK.	CMLNT CPT1200119
2013-3842	05/15/2013 06/13/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	CHRISTOPHER M. KANE SIMON GLUCK & KANE LLP	ENTRY NO EYD-0105093-3
2013-3843	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ALANA ZUSIS SMITH AMUNDSEN LLC	THERMO PAC LLC - SIMPLY THICK DOCS
2013-3844	05/15/2013 06/13/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	SHANNON BUDNICK STOCK YARDS BANK & TRUST CO	LOUISVILLE REPRODUCTION CENTER, LOUISVILLE, KY - INSP
2013-3845	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	SUSAN PATE, RAC STOCK YARDS BANK & TRUST CO	XORAN TECHNOLOGIES INC - XCAT SYS K061834
2013-3846	05/15/2013 06/13/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	CELGENE CORP - 483, EIR, UNTITLED LTRS, CORR
2013-3847	05/15/2013 06/13/2013	FDA/OC/OES/DFOI/	INEZ CAMPBELL SANDOZ	OWEN MUNFORD, MARIETTA, GA - AUTOJET II K013362
2013-3848	05/15/2013 06/13/2013	CVM/OCD/ NCTR/OD/	DR. WOLFGANG STENGEL EUROPEAN COALITION TO END	SUB CHRONIC TOXICITY STUDY ON TRIPHENYL PHOSPHATE

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			ANIMAL EXPERIMENTS	
2013-3849	05/15/2013 06/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAUREN SILVIS SIDLEY AUSTIN LLP	ODE RESPONSES TO RECIPIENTS ON 7/10/12
2013-3850	05/15/2013 06/13/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOSH LEE FEDERAL PUBLIC DEFENDER ARKANSAS	WEST WARD PHARMACEUTICALS INC, EATONTOWN, NJ - INSP, WARNING LTRS, CORR 1/10 TO PRESENT
2013-3851	05/15/2013 06/13/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	HEATHER GALE OLSSON FRANK & WEEDA	REPORTABLE FOOD REGISTRY - UPDATED INTERNAL INSP GUIDANCE PAGE 7
2013-3852	05/15/2013 06/13/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	MEADE, DORIS.	HILLESTAD PHARMACEUTICALS USA INC, WOODRUFF, WI - 483 7/25-27/12
2013-3853	05/16/2013 06/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dion Brandt TIDI Products, LLC	K962288
2013-3854	05/16/2013 06/14/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE MEDICAL, INC, SYLMAR, CA - INSPECTION RECS 6/8/09
2013-3855	05/16/2013 06/14/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Syring Quality & Regulatory Associates, LLC	K870450
2013-3856	05/16/2013 06/14/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa EXPERIEN GROUP LLC	K961385
2013-3857	05/16/2013 06/14/2013	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	GRALISE - ORPHAN DRUG DESIGNATION
2013-3858	05/16/2013 06/14/2013	FDA/OMPT/OSMP/OOPD/	Rachel Johnson FOI Services, Inc.	HORIZANT - ORPHAN DRUG DESIGNATION
2013-3859	05/16/2013 06/14/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Aaron Sorensen doterra	YOUNG LIVING, SPANISH FORK, UT - 483 (06/15/2012 - 06/22/2012)
2013-3860	05/16/2013	FDA/OMPT/CTP/OD/	Rachel Johnson	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATIONS ISSUED BY CTP (10/30/2012 to 05/10/2013)

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	06/14/2013		FOI Services, Inc.	
2013-3861	05/16/2013 06/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nazmin Khan Khan, Nazmin	DELZICOL - CLINICAL REVIEW, CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICAL REVIEW ETC
2013-3862	05/16/2013 06/14/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHRISTOPHER BERRY ANIMAL LEGAL DEFENSE FUND	ROCK ISLAND REFRIGERATED DISTRIBUTORS INC, PETALUMA, CA - EIRS, CO RESP, WARNING LTRS, ETC LAST 5 YRS
2013-3863	05/16/2013 06/14/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	CHRISTOPHER BERRY ANIMAL LEGAL DEFENSE FUND	STEVEN MAHARTIPETALUMA FARMS; PETALUMA, CA - EIRS, CO RESP, WARNING LTR, ETC
2013-3864	05/16/2013 06/14/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	BRENTON L HORNER HORNER & ASSOCIATES	WORLD HEALTH PRODCTS LLC, SALT LAKE CITY, UT - IMPORT REFUSAL RPT 1/06
2013-3865	05/16/2013 06/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHANNON L TURNER GlaxoSmithKline	GLAXOSITHKLINE - EVRUX, WARE -QUALITY ASSURANCE PROFILE (QAP)
2013-3866	05/16/2013 06/14/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	ROBERT ROMIG NUTRITIONAL LABORATORIES INTL	USANA; NATURE SUNSHINE - EIRS
2013-3867	05/16/2013 06/14/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OMAR S RIVERO Thomas J Henry Law Firm	BRISTOL-MYERS SQUIBB (INHIBITEX INC) - HEPATITIS C BMS-986094 (INX-08189) FORM 1571, FORM 1572, PRE-CLNCL STUDIES, ETC(CERTIFIED)
2013-3868	05/16/2013 06/14/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	mohammad 96A3015, MALLK	TEGRETOL, REMORAN, CELEXA - AERS, RECS
2013-3869	05/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Valentine	K102915, K111862

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	06/17/2013		Elekta Inc.	
2013-3870	05/17/2013 06/17/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/	Anna Edney BLOOMBERG NEWS	MARGARET HAMBURG, MITCHELL ZELLER, LEONA BRENNER-GATI - EMAILS (09/01/2012 - 05/16/2013)
2013-3871	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jens Kristensen kristensen	VIREAD - POST APPROVAL SAFETY DATA
2013-3872	05/17/2013 06/17/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Michael Scott Cognate BioServices, Inc.	PHASE 2 MEDICAL MANUFACTURING, ROCHESTER, NH - EIR, 483 (01/01/2006 - 12/31/2006)
2013-3873	05/17/2013 06/17/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Barry Sands RQMIS Inc.	OLYMPUS GYRUS ACMI, OLYMPUS AMERICA - COMM RE INSPECTIONS, RECALL (05/02/2012 - 05/15/2013)
2013-3874	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stewart Siskin, PharmD Erie County Medical Center Corporation	BLA 103172
2013-3875	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Inst. Cent. For Med. Media.	NDA 22426, NDA 203414
2013-3876	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn WASHBURN, KIMBERLEE	P100047
2013-3877	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jens Kristensen kristensen	HESPERA - POST MARKETING SAFETY DATA
2013-3878	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Lim Meng How Crystal Aesthetics	BACTOLAC PHARMACEUTICAL - CERTIFIED REGISTRATION
2013-3879	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY L. GOERSS HODGSON RUSS LLP	ZIMMER DENTAL INC - ZFX DENTAL CAD SYS K121709
2013-3880	05/17/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	SHANNON BUDNICK	LOUISVILLE REPRODUCTIVE CTR, LOUISVILLE, KY - 483 5/6/13

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	06/17/2013		STOCK YARDS BANK & TRUST CO	
2013-3881	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUSTIN DiMARTINO RETROPHIN INC	NOVARTIS PHARMACEUTICALS - SYNTOCINON (OXYTOCIN NASAL SPRAY) NDA 12/285 CLNCL RVV, MEDICAL RVW
2013-3882	05/17/2013 06/17/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	GRAY, SCHERLY D	CMPLNT 132014
2013-3883	05/17/2013 06/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHELLY S. JOCK LAW OFFICES OF RALPH C JONES	OLYMPUS GYRUS ACMI INC - WARNING LTRS, INSP, 7/10 TO 8/2/12
2013-3884	05/17/2013 06/17/2013	FDA/OF/CFSAN/OCD/EOS/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	WACKER BIOCHEM CORP - GRN 000074
2013-3885	05/17/2013 06/17/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	SHELLY S. JOCK LAW OFFICES OF RALPH C JONES	OLYMPUS - ENDOSCOPIC ELECTROSURGICAL UNIT RECALL
2013-3886	05/17/2013 06/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	CNF DESMO PK 200301 - 1/03 TO PRESENT
2013-3887	05/20/2013 06/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Henry Dao HSP USA LLC	K100918, K123072
2013-3888	05/20/2013 06/18/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Brian Duncan Brian Duncan	SANDOZ, WILSON, NC - 483 (03/01/2013 - 05/17/2013)
2013-3889	05/20/2013 06/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patrick Mevs Martin Clearwater & Bell, LLP	TEMODAR - CLINICAL TRIAL RECS

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2013-3890	05/20/2013 06/18/2013	FDA/OO/OHR/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	MARY CAROLE CRANE MUNSON ROWLETT MOORE BOONE	INDIVIDUAL RECS (CERTIFIED)
2013-3891	05/20/2013 06/18/2013	FDA/OO/OHR/	DANIEL H MOSS JOELSON ROSENBERG MOSS COHEN WARREN & DRASNIN PLC	INDIVIDUAL RECS
2013-3892	05/20/2013 06/18/2013	FDA/OO/OHR/	DARIN L RUMER JOSEPH GREENWALD & LAAKE PA	INDIVIDUAL RECS
2013-3893	05/20/2013 06/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	ORGANON - HTLV-I P21E ANTIGEN (HUMAN T-LYMPHOTROPIC VIRUS I & II) APRVL LTR
2013-3894	05/20/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	MERCK SANTE SAS - CYANOKIT (HYDROXOCOBALAMIN) NDA 22-041/S008,S009 APRVL LTR
2013-3895	05/20/2013 06/18/2013	FDA/OGROP/ORASW-FO/NYK-DO/NYK-DCB/	TAKACS, TRACI	FEDERAL LABORATORIES CORP, ALDEN, NY - INSPS, HEALTH VIOLATIONS, INSP RESULTS LAST 15 YRS
2013-3896	05/20/2013 06/18/2013	ORA/ORM/ ORA/ORM/	THOMPSON, RAY	HUMAN DRUG, HUMAN MEDICAL DVC FIRMS - GMP, GLP, GCP INSPS 1/13 TO 3/13
2013-3897	05/20/2013 06/18/2013	FDA/OC/OES/DFOI/	CROSBY T-50417, COURTNEY	LIST OF DRUG AND HEALTH AIDS RECALLS
2013-3898	05/20/2013 06/18/2013	FDA/OF/CFSAN/OCD/EOS/	MCKENZIE #300416, LEROY A	EDIBLE PROTEIN FIBERS, TEXTURIZED FOOD PRODS, PROCESSED POULTRY PRODS, ETC - COMPOSITION QUALITY STANDARDS
2013-3899	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 062-737
2013-3900	05/21/2013	FDA/OGROP/ORASW-FO/MIN-	Jake Lovato, through his counsel	MEDTRONIC ENPULSE IPG - RECALL RECS; MEDTRONIC

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	06/19/2013	DO/MIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/OE/ ORA/OE/	the Kelin Law Firm P.C. Kelin Law Firm P.C.	PACEMAKERS AND LEADS - RECALL CLASSIFICATION LETTERS; RECALL EFFECTIVENESS CHECKS; ETC (02/20/2004 - 05/20/2013)
2013-3901	05/21/2013 06/19/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (05/13/2013 - 05/17/2013)
2013-3902	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	PMA 890023 S 7
2013-3903	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K063359
2013-3904	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61490
2013-3905	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Omobola Mudasiru ENVIRON International Corporation	LIBRIUM NDA
2013-3906	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61395
2013-3907	05/21/2013 06/19/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Prashanth Jayaram Prashanth Jayaram	CARDIOMEMS - WARNING LETTER CORR (06/15/2012 - 05/20/2013)
2013-3908	05/21/2013 06/19/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OF/CFSAN/OCD/EOS/ ORA/ORM/ ORA/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES
2013-3909	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62901

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2013-3910	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61490
2013-3911	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62901
2013-3912	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 61395
2013-3913	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62738
2013-3914	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 62732
2013-3915	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Benita Chappell Cericon, LLC	K111275
2013-3916	05/21/2013 06/19/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCDEOS/ ORA/ ORA/ FDA/OC/OPP/OP/ FDA/OGROP/OIP/	Joseph L. Satran The Huffington Post	MSFA - INTERNAL EMAILS, FAXES, EMAIL ETC
2013-3917	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Jump STRYKER CORPORATION	K123188 SUMMARY
2013-3918	05/21/2013 06/19/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SEA-	Doe J	INDI VIDUAL RECS

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		DO/SEA-CB/		
2013-3919	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Holly Lambert Holly Lambert	K023967, K014234
2013-3920	05/21/2013 07/02/2013	FDA/OC/OPP/OP/	Peter Spaulding Peter Spaulding	PETER LURIE - CORR WITH PUBLIC CITIZEN (08/01/2011 - 05/17/2013)
2013-3921	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Spaulding Peter Spaulding	DR PASCUAL-LEONE - ABSENCE OR RECUSAL FROM 2/10/12 NEUROLOGICAL DEVICES PANEL
2013-3922	05/21/2013 06/19/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ROBERT KING FDANEWS	S & B PHARMA (DBA NORAC PHARMA), AZUSA, CA; MARIETTA CORP, VERNON, CA; PHYSICIANS FORMULA INC, CITIOOF INDUSTRY, CA, ETC - 483S 4/1-30/13
2013-3923	05/21/2013 06/19/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	MILBAR LABORATORIES INC, EAST HAVEN, CT; TOM'S OF MAINE INC, SANFORD, ME; IMMUCELL CORP, POTLAND, ME, ETC - 483S 4/1-30/13
2013-3924	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ROBERT KING FDANEWS	MEDSTRONIC NEUROMODULATION, MINNEAPOLIS, MN; NE'S INK INC, WAUKESHA WI; CEDARBURG PHARMACEUTICALS INC, GRAFTON, WI, ETC - 483S 4/1-30/13
2013-3925	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	MED PREP CONSULTING INC, TINTON FALLS, NJ; FRUTAROM USA INC, NORTH BERGEN, NJ.; P F LABORATORIES INC, TOTOWA, NJ, ETC - 483S 4/1-30/13
2013-3926	05/21/2013 06/19/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	TRIAD ISOTOPES INC, MOBILE AL; CARDINAL HEALTH 414 LLC, BIRMINGHAM, AL; PETER SCHIFF ENTERPRISES, COOKEVILLE, TN, ETC - 483S 4/1-30/13
2013-3927	05/21/2013 06/19/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	TOPIDERM INC, NORTH AMITYVILLE, NY; JEROME STEVENS PHARMACEUTICALS INC, BOHEMIA, NY; BLUE LIGHT INC, ITHACA, NY, ETC - 483S 4/1-30/13
2013-3928	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	AIR LIQUIDE ELECTRONICS US LP, MORRISVILLE, PA - 483S 4/1-30/13
2013-3929	05/21/2013 06/19/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	GENERITECH CORP, FRESNO, CA; HOTSPUR TECHNOLOGIES, MOUNTAIN VIEW, CA; CONNECT IMAGING INC, HONOLULU, HI - 483S 4/1/30/13
2013-3930	05/21/2013 06/19/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	WARNER CHILCOTT COMPANY LLC, FAJARDO, PR; FENWAL A FRESNIUS-KABY CO, MARICAO, PR - 483S 4/1/30/13
2013-3931	05/21/2013 06/19/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	OMEGA TECH LABS LLC, GARDEN DITY, ID; SKIN BIOLOGY INC, BELLEVUE, WA; ACUTE INNOVATIONS LLC, HILLSBORO OR, ETC - 483S 4/1/30/13
2013-3932	05/21/2013 06/19/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	CLINICAL SPECIALTIES COMPOUNDING PHARMACY, AUGUSTA, GA; SANDOZ INC, WILSON, NC; ENCOMPASS

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				GROUP LLC, MCDONOUGH, GA - 483S 4/1-30/13
2013-3933	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	PINK INC (DBA HEARTEN), RICHMOND, VA; BELL-MORE LABORATORIES INC, HAMPSTEAD, MD - 483S 4/1-30/13
2013-3934	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	FINISH LINE INC, BENSENVILLE, IL; VVVF ILLINOIS SERVICES LLC, MONTGOMERY, IL; CONCEPT LABORATORIES, INC, CHICAGO, IL, ETC - 483S 4/1-30/13
2013-3935	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	HITACHI MEDICAL SYSTEMS AMERICA INC, TWINSBURG, OH; SO-LOW ENVIRONMENTAL EQUIPMENT CO INC, CINCINNATI, OH; ASTRO MEDICAL DEVICES, MENTOR, OH - 483S 4/1-30/13
2013-3936	05/21/2013 06/19/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	BEAUTY MANUFACTURING SOLUTIONS CORP, DALLAS, TX; DPT LABORATORIES LTD, SAN ANTONIO, TX; APOTHECURE INC, DALLAS, TX, ETC - 483S 4/1-30/13
2013-3937	05/21/2013 06/19/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	FISCHER MEDICAL TECHNOLOGIES INC, BROOMFIELD, CO; CAO GROUP INC, WEST JORDAN, UT - 483S 4/1-30/13
2013-3938	05/21/2013 06/19/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	AMERIFLO CORP, CARMEL, IN; HEALTHMARK INDUSTRIES, CO INC, FRASER, MN
2013-3939	05/21/2013 06/19/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	TROPICHEM RESEARCH LABS INC, JUPITER, FL; MEDICAL ENERGY INC, PENSACOLA, FL; ZANDER SCIENTIFIC INC, VERO BEARCH, FL - 483S 4/1-30/13
2013-3940	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	PROMED EXPORTS PRIVATE LTD, VILLAGE KHERA NIHLA, INDIA; ALEMBIA LTD, VADODARA, INDIA; RUBICON RESEARCH PRIVATE LTD, KAYLAN, INDIA, ETC - 483S 4/1-30/13
2013-3941	05/21/2013 06/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	TORINER SAS MONTBONNOT, ST MARTIN, FRANCE; HUBEI WEIKANG PROTECTIVE PRODUCTS CO LTD, XIANTAO CITY, CHINA; WONJIN MULSAN CO LTD, INCHEON REPUBLIC OF SOUTH KOREA, ETC - 483S 3/1-30/13
2013-3942	05/21/2013 06/19/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ROBERT KING FDANEWS	VVF KANSAS SERVICES LLC, KANSAS CITY, KS; LLOYD INC OF IOWA, SHENANDOAH, IA; EMERALD 3 ENTERPRISE INC, CAMDENTON, MO, ETC - 483S 4/1-30/13
2013-3943	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jake McDowell The Weinberg Group Inc.	NDA 203826 SBA
2013-3944	05/21/2013	FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert	TAXOTERE - NOTICES, LETTERS, REPORTS RE

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2013-3945	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal, Inc	AVASTIN - NOTICES, LETTERS, REPORTS, ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3946	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S. Gilbert Perfectly Legal, Inc.	HERCEPTIN - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3947	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal, Inc	ALOXI - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3948	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S. Gilbert Perfectly Legal Inc	VELCADE - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3949	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc	MABTHERA - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3950	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc.	MHRA - INFORMATION PROVIDED TO FDA RE NON-FDA CANCER DRUGS
2013-3951	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S. Gilbert Perfectly Legal Inc	GEMZAR - NOTICES, LETTERS, REPORTS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3952	05/21/2013 06/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	NDA 020597

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2013-3953	05/22/2013 06/20/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	ABDALA F KALIL MD, VITALITY INSTITUTE - RECS
2013-3954	05/22/2013 06/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	BRUCE C HERRON LOSCO & MARCONI PA	RITCHIE C SHOEMAKER MD, POCOMOKE CITY, MD - CMPLNTS, STUDIES, RPTS, ETC
2013-3955	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	GALDERMA LABS LP - CLOBEX (CLOBETASOL PROPIONATE) NDA 21-835; PADDOCK LLC - CLOBETASOL PROPIONATE ANDA 90-898 SBA, MOR, LBLG, ETC
2013-3956	05/22/2013 07/12/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JESSHILL E LOVE ESQ ROPERS MAJESKI KOHN & BENTLEY	FUJINO ENTERPRISES INC (DBA BLUE OCEAN SMOKEHOUSE), PRINCETON-BY-THE-SEA, CA - LICENSE STATUS, WARINGS, VIOLATIONS, ETC
2013-3957	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	OLIVIA M FLEMING ESQ BARNES & THORNBURG LLP	BIOLASE TECHNOLOGY INC - WATERLASE MD ER,CR:YSGG K083927
2013-3958	05/22/2013 06/20/2013	FDA/OC/OES/DDM/	JOHN DILLARD OFW LAW	DKT 1980P-0226
2013-3959	05/22/2013 06/20/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 1975N-0244
2013-3960	05/22/2013 06/20/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Richard Dijkman Protocol Naturals	LIQUID HEALTH, MURIETTA, CA - EIR, WARNING LETTER RESPONSE (07/08/2012 - 01/03/2013)
2013-3961	05/22/2013 06/20/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan M. Bonapace ALEXION PHARMACEUTICALS	BOEHRINGER INGELHEIM PHARMA GMBH & CO - WARNING LETTER, 483, COMPANY RESPONSE ETC (11/01/2012 - 05/17/2013)
2013-3962	05/22/2013	FDA/OF/CFSAN/OCD/EOS/	ADAM DIEDERICH	KEATON WALKER, TRAVIS BOUSLOG, RESPONSIBLE

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	06/20/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	SCHIFF HARDIN LLP	TRANSPORTATION, SIGOURNEY, IA - RECS 1/10 TO PRESENT
2013-3963	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ryan Lambert New Look Laser College	K110370, K033259
2013-3964	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kate Vassilkova INDEPENDENCE LEGAL SUPPORT	INACTIVE INGREDIENT GUIDE (01/01/1998 - 12/31/1999)
2013-3965	05/22/2013 06/20/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ADAM DIERERICH SCHIFF HARDIN LLP	ROSEWOOD FARMS, SIGOURNEY, IA - RECS 1/08 TO RPRESENT
2013-3966	05/22/2013 06/20/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ADAM DIEDERICH SCHIFF HARDIN LLP	DAVID RAINS, RAINS NATURAL MEAT, GALLATIN, MO - RECS 1/08 TO PRESENT
2013-3967	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHERENE J. MASTROIANNI OLYMPUS AMERICA INC	PENTAX - VIDEO PROCESSOR EPK-15010 K122470
2013-3968	05/22/2013 06/20/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	DAM DIEDERICH SCHIFF HARDIN LLP	WEST LIBERTY FOODS, MOUNT PLEASANT FOODS, SIGOURNEY FOODS, SIGOURNEY, IA - RECS 1/08 TO PRESENT
2013-3969	05/22/2013 06/20/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Imani Gandy RH Reality Check	7/19/12 MTG BTWN JANET WOODCOCK AND RESEARCH AND CHIEF MEDICAL OFFICERS OF PHARMACEUTICAL FIRMS; 3/22-23/12 MEETING BTWN JANET WOODCOCK AND RESEARCH AND CHIEF MEDICAL OFFICERS, JANE AXELRAD ETC; 6/10/10 MTG BETWEEN JOSH SHARFSTEIN AND TEVA DRUGS RE GENERIC DRUGS - MINUTES, NOTES, PRESENTATION MATERIALS
2013-3970	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	CINRYZE - AER
2013-3971	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Terri Meredith NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS	NDC - NUMBER OF LABELER CODES WITH 5 OR LESS DIGITS ETC

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2013-3972	05/22/2013 06/20/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S, INSPECTIONS, EIR IN EXCEL FORMAT 4/16/13 TO 5/18/13
2013-3973	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	COVIDIEN INC - PATIENT RETURN ELECTRODE; GROUNDING PADS INJURIES 1/95 TO PRESENT
2013-3974	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Todd Cartee Penn State Hershey Medical Center	LMX-4, 20% BENZOCAINE CREAM - APPROVAL LABELS
2013-3975	05/22/2013 06/20/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/ OC/OCC/	Bruce Burk CITIZEN	GENETICALLY MODIFIED ORGANISMS - TESTS, REVIEWS, STUDIES ETC
2013-3976	05/22/2013 06/20/2013	CVM/OCD/	HUGHES, LAURA .	DLIMONENE - AER
2013-3977	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Burgan Smith & Nephew, Inc.	K110546, K101793, K081584 ETC
2013-3978	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	RONALD KALISH STEINBERG GOODMAN & KALISH	SMITH & NEPHEW - EMPERION FEMORAL COMPONENT APRVL, EIR, LBLG ETC 2000 TO PRESENT
2013-3979	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	VIK BAJNATH ARTHREX INC	MW #5029745
2013-3980	05/22/2013 07/22/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	MARK F. SCHOTTINGER KIRKLAND & ELLIS LLP	EASTERN MAGNESIA TALC CO - STUDIES, CORR, INPS, ETC 1967 TO 1990
2013-3981	05/22/2013 06/20/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Doe J	INDIVIDUAL RECS

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2013-3982	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIMBERLY MANHARD ARDEA BIOSCIENCES	CLNCL TRIAL SITE CLOSURE
2013-3983	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	COOKS INC - ZILVER PTX DRUG ELUTING PERIPHERAL STENT P100022 MINS, RVWS MEMOS, TELEPHONE MEMOS
2013-3984	05/22/2013 06/20/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	MIMEDX GROUP INC - EIRS, 483S, UNTITLED LTRS 1/10 TO PRESENT
2013-3985	05/22/2013 06/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBI PERRY NORTH AMERICAN RESCUE LLC	COMBAT MEDICAL SYSTEMS LLC - COMBAT READY CLAMP K130482
2013-3986	05/22/2013 06/20/2013	FDA/OC/OES/DFOI/ ORA/OCI/ ORA/OCI/	BRANDON L. BOGLE LEVIN PAPANTONIO THOMAS ET AL	REPORTED VIOLATIONS OF 21 CFR 1/08 TO PRESENT
2013-3987	05/22/2013 06/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	WOOSTER, ANNALEE	RESTYLANE, RESTYLANE-L - AERS 1/04 TO PRESENT
2013-3988	05/22/2013 06/20/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	NANCY WATZMAN SUNLIGHT FOUNDATION	CFSAN MTG MINS 1/4/11 TO 5/20/13
2013-3989	05/22/2013 06/20/2013	OC/OL/	NANCY WATZMAN SUNLIGHT FOUNDATION	CORR BETWEEN FDA & MEMBERS OF CONGRESS RE FOOD MODERNIZATION ACT 1/4/11 TO 5/20/13
2013-3990	05/22/2013 06/20/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARILEE KARTJE Teva Pharmaceuticals	STEVEN WEINMAN, LARRY AUSTIN - 483S 2012, 2013

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2013-3991	05/23/2013 06/21/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Alexion Pharmaceuticals, Smithfield, RI
2013-3992	05/23/2013 06/21/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Abbott Laboratories, Worcester, MA
2013-3993	05/23/2013 06/21/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: AMAG Pharmaceuticals, Inc., Cambridge, MA
2013-3994	05/23/2013 06/21/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Amgen Inc, West Greenwich, RI
2013-3995	05/23/2013 06/21/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Amgen Inc, Woburn, MA
2013-3996	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	NDA 018086 - SBA
2013-3997	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Hariharan PATRIN PHARMA INC	NDA 019452 - SBA
2013-3998	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Cynthia S Gilbert Perfectly Legal Inc	PACLITAX - NOTICES, REPORTS, LETTERS ETC RE MISLABELING (01/01/2009 - 12/31/2012)
2013-3999	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Larry Hamilton THE PROMETHEUS GROUP OF NEW HAMPSHIRE LIMITED	K842514, K864690
2013-4000	05/23/2013 06/21/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Martin Robbins THE GUARDIAN	DR STANISLAW BURZYNSKI, HOUSTON, TX - INSPECTIONS, COMPLIANCE, ENFORCEMENT ETC (01/01/2003 - 05/31/2013)
2013-4001	05/23/2013	FDA/OGROP/ORA/SW-FO/DAL-	Martin Robbins	DR STANISLAW BURZYNSKI, BURZYNSKI RESEARCH

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	06/21/2013	DO/DAL-CB/	THE GUARDIAN	INSTITUTE, BURZYNSKI CLINIC - INSPECTIONS, COMPLIANCE, ENFORCEMENT ETC (01/01/1987 - 12/31/2002)
2013-4002	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Allison Scott ANSON GROUP	K120033, K063692, K063740
2013-4003	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott R. Lambert EMORY UNIVERSITY	IDE G020021
2013-4004	05/23/2013 06/21/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 90358
2013-4005	05/23/2013 06/21/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203098
2013-4006	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	JOHN WALSH JAMES ALEXANDER CORP	APLICARE INC, PRICHARD, WV - EIRS, 483S, RECALLS 5/11 TO PRESENT
2013-4007	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	JOHN WALSH JAMES ALEXANDER CORP	MICROBIOLOGICAL CONSULTANTS INC, WEST VIRGINIA, WV - EIRS, 483S, RECALLS 4/11 TO PRESENT
2013-4008	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/BLT-DO/BLT-CB/	BENDA M GARTZ ELI LILLY & CO	FISHER BIOSERVICES, ROCKVILLE, MD - EIRS 2010 TO PRESENT
2013-4009	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	BRENDA M GARTZ ELI LILLY & CO	TREK DIAGNOSTICS SYSTEMS (DBA THERMO FISHER SCIENTIFIC), SUN PRAIRIE, WI - 483S 2010 TO PRESENT
2013-4010	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/MIN-DO/MIN-CB/	BRENDA M GARTZ ELI LILLY & CO	TREK DIAGNOSTICS SYSTEMS INC (DBA THERMO FISHER SCIENTIFIC), SUN PRAIRIE, WI - EIRS 2010 TO PRESENT
2013-4011	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORAC/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	FISHER CLINICAL SERVICES, GUJARAT, INDIA, ALLENTOWN, PA, BUENOS AIRES, ARGENTINA, ETC - EIRS 2010 TO PRESENT
2013-4012	05/23/2013 06/21/2013	FDA/OGROP/ORAC/CE-FO/CHI-DO/CHI-CB/	BRENDA M GARTZ ELI LILLY & CO	FISHER CLINICAL SERVICES, GUJARAT, INDIA, ALLENTOWN, PA, BUENOS AIRES, ARGENTINA, ETC - 483S 2010 TO PRESENT

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2013-4013	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	THEROMO FISHER SCIENTIFIC (FISHER SCIENTIFIC CO), FAIRPORT, NY, MIDDLETOWN, VA, SHANGHAI, CHINIA, ETC - 483S
2013-4014	05/23/2013 06/21/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	THERMO FISHER SCIENTIFIC (FISHER SCIENTIFIC CO), FAIRPORT, NY, MIDDLETOWN, VA, SHANGHAI, CHINA, ETC - EIRS 2010 TO PRESENT

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2013-4015	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD HAY LAW OFC	ZIMMER - NATURAL NAIL SYS; CEPHALAMEDULARY FERORAL NAIL MDRS
2013-4016	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBBINS	TROVAGENE - HPV HIGH-RISK TEST GEN 1300246
2013-4017	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	PERRIGO ISRAEL - TESTOSTERONE APRVL PKG NDA 203-098
2013-4018	05/23/2013 06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LORI COHEN GREENBERG TRAURIG LLP	SOFRADIM PRODUCTION - UGTEXMESH K033376; DAVOL INC (CR BARD INC) - COLLAMEND IMPLANT K052322; CR BARD INC - PELVISOF ACELLULAR COLLAGEN BIOMESH K031332, ETC
2013-4019	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN W GETSINGER MEDTRONIC	ALLERGAN INC - BOTOX LAST FIVE YRS
2013-4020	05/23/2013 06/21/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANGELA E MCGRAW FLEISHMAN & SHAPIRO PC	MERCK & CO INC - INVANZ RECALL LTR
2013-4021	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JENINIFER HSIEH DEERFIELD INSTITUTE	MANNKIND CORP - AFREZZA COMPLETE RESP LTRS
2013-4022	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	BOEHRINGER INGELHEIM - PRADAXA (DABIGATRAN) CORR
2013-4023	05/23/2013 06/21/2013	FDA/OF/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	FRUITE JUICE, VEGETABLE JUICE - LTRS 1/94 TO PRESENT
2013-4024	05/23/2013	OM/OSS/OPILS/FDAHO/		ORAL HISTORY TRANS - DVD

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	06/21/2013		BYLER, LARIEA	
2013-4025	05/23/2013 06/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	AMBIEN, AMBIEM CR - AERS
2013-4026	05/23/2013 06/21/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0070
2013-4027	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Laura Bleyendaal DePuy Synthes Spine	K071922
2013-4028	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K980431
2013-4029	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K062697
2013-4030	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Donna Stauffer TELA Bio, Inc.	K070560
2013-4031	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Holly Imes MOOG MEDICAL DEVICES GROUP	K121613
2013-4032	05/24/2013 06/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Cubist Pharmaceuticals, Lexington, MA
2013-4033	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joel Chic RGI Medical	INTAVENT LARYNGEAL MASK - 510K SUMMARY
2013-4034	05/24/2013 06/24/2013	FDA/OMPT/CTP/OD/	Ryan Meyer HAGENS BERMAN SOBOL SHAPIRO LLP	TOBACCO PRODUCT ANALYSIS: SCIENTIFIC PUBLIC WORKSHOP - TRANSCRIPT (04/01/2012 - 04/30/2012)
2013-4035	05/24/2013 06/24/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LEXISNEXIS COURTLINK INC	2013-2157
2013-4036	05/24/2013 06/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jessica Sparks Lilley Vanderbilt Children's Hospital	STATIN THERAPY - AERS
2013-4037	05/24/2013 06/24/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Derek Auito MCKENNA LONG & ALDRIDGE	RECALL D-1652-2012

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			LLP	
2013-4038	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joshua M. Robinson Joshua M. Robinson	DR DURRAN - ADVERSE EVENTS
2013-4039	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Langreth BLOOMBERG NEWS	RESULTS OF MEDICAL PRODUCT SAFETY NETWORK SMALL SAMPLE SURVEY RE INTUITIVE DA VINCE SURGICAL SYSTEM
2013-4040	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Lawrence W. Masten, PhD, DABT Lawrence W. Masten, PhD, DABT	PAXIL - AERS
2013-4041	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia S Gilbert Perfectly Legal, Inc.	ZOMETA - NOTICES, REPORTS, LETTERS RE MISLABELING (01/01/2009 - 12/31/2012)
2013-4042	05/24/2013 06/24/2013	FDA/OF/CFSAN/OCDE/EOS/	Amy Shipley Fort Lauderdale Sun Sentinel	PRO SUPPS HYDE, CELLUCOR C4 EXTREME, BSN N.O- XPLODE - AERS, WARNING LETERS (01/01/2010 - 05/15/2013)
2013-4043	05/24/2013 07/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BLA 103649/5107
2013-4044	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cynthia S. Gilbert Perfectly Legal Inc	ELOXATIN - NOTICES, REPORTS, LETTERS RE MISLABELING (1/01/2009 - 12/31/2012)
2013-4045	05/24/2013 06/24/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	David Shaw SHAW, DAVID	ST JUDE MEDICAL IESD UPDATE REPORT TO WARNING LETTER AND 483 RESPONSES (04/14/2013 - 05/22/2013)
2013-4046	05/24/2013 06/24/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Matt Mezvinsky Ridgeback Capital Management, LLC	GILEAD, FOSTER CITY, CA - 483, WARNING LETTER (01/01/2012 - 05/22/2013)
2013-4047	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES INC	ANDA 062-737, 061-490, ANDA 062-738, 061, ANDA 062-901 ETC - LABELING
2013-4048	05/24/2013 06/24/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Chris Lewis Scion Medical Technologies, LLC	ACCESS CARDIOSYSTEMS Z-0199-05, Z-0203-05, Z-0201- 05 ETC - RECALL CORR

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2013-4049	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Dan Michaeli Sirona Dental Systems, Inc.	IMAGING SCIENCES I-CAT FLX SCANNER - CONSUMER COMPLAINT RECS
2013-4050	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	George Kontos SPK	CERVICORE INTERVERTEBRAL DISC - CLINICAL TRIAL RECS
2013-4051	05/24/2013 06/24/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Michael Scott Cognate BioServices, Inc.	CURASCRIP SD, LAKE MARY, FL - FOLLOW UP INSPECTION TO WARNING LETTER
2013-4052	05/24/2013 06/24/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Lisa Torkelson Old Country Farms Co-op	CLOVERLEAF BRAND MUENSTER - DESTRUCTION RECS (4/20/2013 - 05/20/2013)
2013-4053	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Scott Groner TRIS PHARMA INC	HYCODAN - APPROVAL RECS
2013-4054	05/24/2013 06/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Wiard PhysioWave Inc.	ATCOR MEDICAL XCEL PWA/PWV - 510K
2013-4055	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Beau Bassett Pura Vida Investments	JETREA - AERS
2013-4056	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dustin Block IPD Analytics, LLC	ANDA 202571 - EFFECTIVE APPROVAL LETTER
2013-4057	05/24/2013 06/24/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2013-N-0227
2013-4058	05/24/2013 06/24/2013	FDA/OC/OES/DDM/	MERLE ZIMMERMANN AMERICAN HERBAL PRODUCTS ASSOCIATION	DKT FDA-2012-S-1178, FDA-2013-S-0023
2013-4059	05/24/2013 06/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E. CHALKLEY THOMSON REUTERS	CSL BEHRING, BERN SWITZERLAND - EIR, 483, CO RESP 2/12
2013-4060	05/24/2013 06/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	NOVO NORDISK A/S. SOEBORD, DENMARK - 483, EIR, CO RESP 5/12

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2013-4061	05/24/2013 06/24/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	TEVA PHARMACEUTICALS USA INC, MEXICO, MO - 483, EIR, CO RESP 2/12
2013-4062	05/24/2013 06/24/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	NOVARTIS VACCINE & DIAGNOSTICS INC, EMERYVILLE, CA - EIR, 483, CO RESP 3/12
2013-4063	05/24/2013 06/24/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MALLINCKRODT INC, MARYLAND HEIGHTS, MO - EIR, 483, CO RESP 8/12
2013-4064	05/24/2013 08/28/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTLE E. CHALKLEY THOMSON REUTERS	FRESENIUS MEDICAL CARE, OGDEN, UT - EIR, 483, CO RESP
2013-4065	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER CHALKLEY THOMSON REUTERS	BRISTOL MYERS SQUIBB, PRINCETON, NJ - EIR, 483, CO RESP 1/12
2013-4066	05/24/2013 07/09/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MCLAREN HEALTH CARE IRB, BURTON, MI - EIR, 483, CO RESP 7/12
2013-4067	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	JOHN O FLEMING MD, MADISON, WI - EIR, 483, CO RESP 6/12
2013-4068	05/24/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	DAVA PHARMACEUTICALS INC, FORT LEE, NJ - EIR, 483, CO RESP 7/12
2013-4069	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MYLAN PHARMACEUTICALS INC, MORGANTOWN, WV - EIR, 483, CO RESP 7/12
2013-4070	05/24/2013 06/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	ALEXION PHARMACEUTICALS INC, CHESSHIRE, CT - EIR, 483, CO RESP 8/12
2013-4071	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	SANOFI PASTEUR INC, SWIFTWATER, PA - EIR, 483, CO RESP 8/12
2013-4072	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E. CHALKLEY THOMSON REUTERS	MERCK & CO, SPRINGFIELD, NJ - EIR, 483, CO RESP 5/12
2013-4073	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMERICAN NATIONAL RED CROSS, FAIRFAX, VA - EIR, 483, CO RESP 3/12
2013-4074	05/24/2013 06/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	INDICUS PHARMA LLC, RALEIGH, NC - EIR, 483, CO RESP 9/12
2013-4075	05/24/2013 06/26/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E. CHALKLEY THOMSON REUTERS	CARDINAL HEALTH LLC, LAS VEGAS, NV - EIR, 483, CO RESP 9/12
2013-4076	05/24/2013 06/24/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E. CHALKLEY THOMSON REUTERS	BAXTER PHARMACEUTICALS SOLUTIONS, BLOOMINGTON, IN - EIR, 483, CO RESP 9/12
2013-4077	05/24/2013	FDA/OGROP/ORA/CE-FO/DET-	WALTER E. CHALKLEY	ALL AMERICAN WELDING SUPPLY INC, PLYMOUTH, IN -

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	06/24/2013	DO/DET-CB/	THOMSON REUTERS	EIR, 483, CO RESP 9/12
2013-4078	05/24/2013 06/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AIRGAS USA LLC, DALLAS, TX - EIR, 483, CO RESP 9/12
2013-4079	05/27/2013 06/24/2013	CVM/OCD/ FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Tom Amoss Tom amoss	AHC PRODUCTS, WINCHESTER, KY - INSPECTION RECORDS, ADVERSE EVENTS (12/01/2011 - 05/22/2013)
2013-4080	05/27/2013 06/24/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Robert Langreth BLOOMBERG NEWS	CORR BETWEEN FDA AND INTUITIVE SURGICAL RE JAN 2013 MEDICAL PRODUCT SAFETY NETWORK SMALL SAMPLE SURVEY RE DA VINCE SURGICAL SYSTEM ETC
2013-4081	05/27/2013 06/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	David Shaw SHAW, DAVID	ST JUDE MEDICAL - CORR, RESPONSES TO 6/26/09 WARNING LETTER FOR NEUROMODULATION DIVISION AND FACILITIES IN PLANO, TX AND HACKETTSTOWN, NJ
2013-4082	05/27/2013 06/24/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	Joshua Valero Capstone Law APC	MOTT'S LLP NUTRIENT CLAIM PETITIONS (05/23/2008 - 05/23/2013)
2013-4083	05/27/2013 06/24/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kip Nelson SMITH MOORE LEATHERWOOD LLP	NESHER PHARMACEUTICALS - FIELD ALERT RECS, MEETING RECS, 483 (01/01/2010 - 05/23/2013)
2013-4084	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc	ICLUSIG - VOLUNTARY DIRECT REPORTS
2013-4085	05/28/2013 06/25/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: AstraZeneca Pharmaceuticals LP, Westborough, MA
2013-4086	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tom J Healy VITALOGRAPH (IRELAND) LTD	VITALOGRAPH - EIR (09/12/2011 - 09/16/2011)
2013-4087	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA20427

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2013-4088	05/28/2013 06/25/2013	ORA/ORM/ ORA/ORM/	Jason DeYoung DeYoung, Jason	HOSPITALS INSPECTED IN MI, IN, OH (05/04/2010 - 05/23/2013)
2013-4089	05/28/2013 06/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Alexion Pharmaceuticals, Cheshire, CT
2013-4090	05/28/2013 06/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Bristol-Meyers-Squibb, Devens, MA
2013-4091	05/28/2013 06/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Biogen Idec, Cambridge, MA
2013-4092	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	CTP FOIA REQUEST LOG 06/22/2009 - 05/24/2013
2013-4093	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121174
2013-4094	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102003
2013-4095	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/	Bowman Cox Elsevier Business Intelligence	HOSPIRA HEALTHCARE INDIA - CORR RE ADDITIONAL AND REMOVAL OF PRODUCTS (01/01/2012 - 05/24/2013)
2013-4096	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121943
2013-4097	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Johnston Johnston, Kevin	NDA 201922 - SBA
2013-4098	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Natalie Morrison BIOPHARM INSIGHT	ASTRAZENICA, MACCLESFIELD - 483, RESPONSE MARCH 2012
2013-4099	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gloria Reyes Gloria Reyes International	NDA 020240

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Journalism	
2013-4100	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran Associates	K122356
2013-4101	05/28/2013 06/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gloria Reyes Gloria Reyes International Journalism	NDA 019886
2013-4102	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BTran Tran & Associates	K090363
2013-4103	05/28/2013 06/25/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	Wang Tangshan Huiyuan Food Co., Ltd.	TANGSHAN HUIYUAN FOOD CO LTD, CHINA - IMPORT INFORMATION
2013-4104	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	Christopher Brennan WESTLAW COURT EXPRESS	RECORDS PROVIDED TO KATHERINE EBAN RE DIRTY MEDICINE
2013-4105	05/28/2013 06/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Richard Chun the Wood Burditt group	M50-0271820-8, M50-0281400-7 - CFSAN RECORDS
2013-4106	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Richard Wilson Hartford Steam Boiler Inspection & Insurance Co	ROYAL FOOD DISTRIBUTORS, HEIGHTSTOWN, NJ - CONDEMNATION RECS (04/01/2012 - 06/30/2012)
2013-4107	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Lauren DePompei Ben Venue Laboratories	WELCH, HOLME AND CLARK, NEWARK, NJ - EIR (10/01/2010 - 01/01/2011)
2013-4108	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112506
2013-4109	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOGS 4/29/3-5/3/13
2013-4110	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4111	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOGS 5/6-10/13

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2013-4112	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 5/6-10/13
2013-4113	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 4/29/13-5/3/13
2013-4114	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4115	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/6-10/13
2013-4116	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/6-10/13
2013-4117	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 4/29/13-5/3/13
2013-4118	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/6-10/13
2013-4119	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/6-10/13
2013-4120	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4121	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 4/29/13-5/3/13
2013-4122	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/6-10/13
2013-4123	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/6-10/13
2013-4124	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 4/29/13-5/3/13
2013-4125	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIRA REQUESTS 5/6-10/13
2013-4126	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 4/29/13-5/3/13

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2013-4127	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 4/29/13-5/3/13
2013-4128	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/6-10/13
2013-4129	05/28/2013 06/25/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	MITCHELL S FUERST ESQ FUERST ITTLEMAN PL	DKT 1996N-0050, ADVANCED NOTICE OF PROPOSED RULEMAKING FOR THE REGULATION OF MEDICAL FOODS, ETC
2013-4130	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 4/29/13-5/3/13
2013-4131	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	GLADYS B TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 5/6-10/13
2013-4132	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 4/29/13-5/3/13
2013-4133	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	KLEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/6-10/13
2013-4134	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	HOLLY RAMIREZ BOSTON SCIENTIFIC CORP	BOSTON SCIENTIFIC CORP - RIO ASPIRATION CATHETER K051880
2013-4135	05/28/2013 07/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KEVIN H KONO DAVIS WRIGHT TREMAINE LLP	MOON MARINE, CUPERTINO, CA - EIR 4/16/12-5/8/12
2013-4136	05/28/2013 06/25/2013	FDA/OF/CFSAN/OCD/EOS/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	DEHYDRATED BEET (BEET POWDER) AND TUMERIC - RECS
2013-4137	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ANTOON, DAVID	INTUITIVE SURGICAL INC - ROBOTIC DA VINCI DVC INVESTIGATION, CLEVELAND CLINIC FOUNDATION SURGERY FINDINGS
2013-4138	05/28/2013 06/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT POLLOCK LACHMAN CONSULTANT SERVICES INC	ARGENT, NEXGEN, MANCHESTER PHARMS - INVERSINE (MECAMYLAMINE HCL) NDA 10-251 RECS, MEDICAL NECESSITY
2013-4139	05/28/2013 06/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PETER S REICHERTZ SHEPPARD MULLIN RICHTER &	VASOPRESSIN INJ - AERS

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HAMPTON	
2013-4140	05/28/2013 06/25/2013	FDA/OF/CFSAN/OCD/EOS/	IOVATE HEALTH SCIENCES RESEARCH INC	CAERS 153519, 158001
2013-4141	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS CORP	ACCU-CHEK COMBO K111353, ACCU-CHEK INFORM II K121679, ACCU-CHEK NANO SMARTVIEW SYS K113131, ETC
2013-4142	05/28/2013 06/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANGIE BEYER AIRLIQUIDE	AGA LINDE HEALTHCARE - MEDICYL-E-LITE PORTABLE OXYGEN SYS K033897
2013-4143	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	DANIEL M SULLIVAN MD, MELISSA ALSINA MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 8/04
2013-4144	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	HUSSAIN I SABA MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 2/06
2013-4145	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	HUSSAIN I SABA MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 5/05
2013-4146	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	VERNON K SONDAK MD, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 10/11
2013-4147	05/28/2013 06/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	JAVIER PINILA-IBARZ, H LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, TAMPA, FL - EIR, 483, CO RESP 9/12
2013-4148	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	STERIS ISOMEDIX SERVICES INC, SOUTH PLAINFIELD, NJ - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4149	05/28/2013 06/25/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JOHN WALSH JAMES ALEXANDER CORP	PLASTICS TECHNOLOGY LABORATORIES INC, PITTSFIELD, MA - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4150	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	MOCON INC, MINNEAPOLIS, MN - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4151	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	GILBRALTAR LABS, FAIRFIELD, NJ - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4152	05/28/2013 06/25/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	JOHN WALSH JAMES ALEXANDER CORP	WHITEHOUSE ANALYTICAL LABS, WHITEHOUSE, NJ - EIRS, 483S, RECALL RECS 10/08 TO PRESENT
2013-4153	05/28/2013	FDA/OGROP/ORA/CE-FO/NWJ-	JOHN WALSH	WHITEHOUSE ANALYTICAL LABS, WHITEHOUSE, NJ - EIRS,

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	06/25/2013	DO/NWJ-CB/	JAMES ALEXANDER CORP	483S, RECALL RECS 5/11 TO PRESENT
2013-4154	05/28/2013 06/25/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	JOHN WALSH JAMES ALEXANDER CORP	OLIVER-TOLAS HEALTHCARE PACKAGING, FEASTERVILLE, PA - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4155	05/28/2013 06/25/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	JOHN WALSH JAMES ALEXANDER CORP	MIDWEST FILTRATION CO, CINCINNATI, OH - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4156	05/28/2013 06/25/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	JOHN WALSH JAMES ALEXANDER CORP	UFP TECHNOLOGIES, DENVER, CO - EIRS, 483S, RECALL RECS 5/11 TO PRESENT
2013-4157	05/28/2013 06/25/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (5/20/2013 - 5/24/2013)
2013-4158	05/29/2013 06/26/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0471
2013-4159	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme, Northborough, MA
2013-4160	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme Science Center, Framingham, MA
2013-4161	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme, Allston, MA
2013-4162	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Genzyme, Cambridge, MA
2013-4163	05/29/2013 06/26/2013	ORA/ ORA/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	Kenneth Lum Seafood Products Association	LABORATORY REPORT 803495
2013-4164	05/29/2013 06/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B. burgess BURGESS, BERNIE	TRANSCRIPT OF TELEPHONE CALL 1/24/07 FROM DAN-MY CHU RE COMPLAINT
2013-4165	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	HILLUSA CORPORATION HILLUSA CORPORATION	K940975

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2013-4166	05/29/2013 06/26/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Tom Standifer Self	HAAS PHARMACEUTICALS, LLC - INSPECTIONS, FILINGS, APPLICATIONS ETC (01/01/1985 - 05/28/2013)
2013-4167	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Saagar Patel Whitney Medical Solutions	K820692
2013-4168	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kim Thorson Medical Products Laboratories, Inc.	K040098
2013-4169	05/29/2013 06/26/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Steve Schroeder Schroeder Law	EVANGER'S DOG AND CAT FOOD, WHEELING, IL - ALL RECS (01/01/2010 - 05/28/2013)
2013-4170	05/29/2013 06/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Kristin Hinton METHAPHARM INC	FAERS REPORTS
2013-4171	05/29/2013 06/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Sean Stewart Concordia University Wisconsin School of Pharmacy	STATINS - CASE REPORTS
2013-4172	05/29/2013 06/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	B. Burgess B. Burgess	INTERNAL MEMO OR CONSULT REFERENCED IN LETTER FROM MS AUTOR
2013-4173	05/29/2013 06/26/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Kirsty Barnes BIOPHARM INSIGHT	WOCKHARDT LIMITED, AURANGABAD - 483, WARNING LETTER
2013-4174	05/29/2013 06/26/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Kirsty Barnes BIOPHARM INSIGHT	EXEMPLAR - 483, WARNING LETTER

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/		
2013-4175	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-7948
2013-4176	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2554 - REQUEST LETTER ONLY
2013-4177	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2842 - REQUEST LETTER ONLY
2013-4178	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3447 - REQUEST LETTER ONLY
2013-4179	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2987 - REQUEST LETTER ONLY
2013-4180	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3068 - REQUEST LETTER ONLY
2013-4181	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3003 - REQUEST LETTER ONLY
2013-4182	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3182 - REQUEST LETTER ONLY
2013-4183	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KILPATRICK, PETE	BIO-MEDICAL RESEARCH LTD, WEST GALWAY, REPUBLIC OF IRELAND - NEURO TECH TYPE 410 K024258
2013-4184	05/29/2013 06/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	KATHY A STETTS KEMP JONES & L COULTHARD	SUNRISE HOSPITAL & MEDICAL CENTER, LAS VEGAS, NV - MDRS, LTRS, RECALLS, ETC 1/1/09 TO 12/31/10
2013-4185	05/29/2013 06/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAELE K POWERS BRASSEL ALEXANDER & RICE LLC	JOHN HOPKINS MEDICINE - PHARMACODYNAMIC TRIAL OF PRE-PROSTATECTOMY LOVASTATIN IND, AMENDMENTS, MINS, ETC
2013-4186	05/29/2013 06/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DDM/	CATHERINE M DICKENSON BRYAN CAVE LLP	DKT 2007P-0190

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2013-4187	05/29/2013 06/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	VETTER, RAVENSBURG, SCHUENTZENTRASSE, GERMANY - EIRS 10/29/12-11/9/12
2013-4188	05/29/2013 06/26/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	BJIAN ESFANDIARI BAUM HEDLUND PC	POMONA VALLEY HOSPITAL MEDICAL CENTER - DRAFT & FINAL RPT, NOTES, VIOLATIONS, ETC 9/24/12
2013-4189	05/29/2013 06/26/2013	ORA/ORM/ ORA/ORM/	DAVID P JORDAN THOMSON REUTERS	LIST OF FOREIGN & DOMESTIC INSP 10/12 TO PRESENT
2013-4190	05/29/2013 06/26/2013	CVM/OCD/	AMI V GADHIA CONSUMERS UNION	NARMS RETAIL MEAT PROGRAM - LABEL CLAIMS 1/03 TO 2011
2013-4191	05/29/2013 06/26/2013	FDA/OC/OES/DFOI/	ANNE WEISMANN CITIZENS FOR RESPONSIBILITY & ETHICS IN WASHINGTON	COST OF EACH TRIP & COST OF TRAVEL BY FDA EMPLOYEE - RECS 10/12 TO PRESENT
2013-4192	05/30/2013 06/27/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SARAH KARLIN ELSEVIER PINK SHEET	MCMI REGULATORY SYMPOSIUM - LESSONS LEARNED FROM H1N1 TO ENHANCE TODAY'S PANDEMIC INFLUENZA VACCINE PREPAREDNESS SLIDE PRESENTATION 5/29/13
2013-4193	05/30/2013 06/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	5N PLUS LUBECK GMBH, LUBECK, GERMANY - EIR, 483, CO RESP 7/12
2013-4194	05/30/2013 07/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	COMMONWEALTH SERUM LABORATORIES (CSL) LTD, PARKVILLE, AUSTRALIA - EIR, 483, CO RESP 4/22
2013-4195	05/30/2013 06/27/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	220 LABORATORIES INC, RIVERSIDE, CA - EIR, 483, CO RESP 6/12
2013-4196	05/30/2013 06/27/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	21ST CENTURY ONCOLOGY INC, NAPLES, FL - EIR, 483, CO RESP 4/12
2013-4197	05/30/2013 06/27/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	21ST CENTURY ONCOLOGY INC, PORT CHARLOTTE, FL - EIR, 483, CO RESP 4/12
2013-4198	05/30/2013 06/27/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AAI PHARMA ANALYTICAL SERVICES ST LOUIS INC, AFFTON, MO - EIR, 483,CO RESP 2/12
2013-4199	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	AAI PHARMA SERVICES, EDISON, NJ - EIR, 483, CO RESP 3/12
2013-4200	05/30/2013	FDA/OGROP/ORA/SE-FO/ATL-	WALTER E CHALKLEY	AAI PHARMA SERVICES, WILMINGTON, NC - EIR, 483, CO

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	06/27/2013	DO/ATL-CB/	THOMSON REUTERS	RESP 3/12
2013-4201	05/30/2013 06/27/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	AARON INDUSTRIES INC, LYNWOOD, CA - EIR, 483, CO RESP 4/12
2013-4202	05/30/2013 06/27/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ABBOTT BIOTECHNOLOGY LTD, BARCELONETA, PR - EIR, 483, CO RESP 7/12
2013-4203	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACCELERATED ANALYTICAL LABORATORIES INC, MILWAUKEE, WI - EIR, 483, CO RESP 6/12
2013-4204	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACTAVIS ELIZABETH LLC, ELIZABETH, NJ - EIR, 483, CO RESP 1/12
2013-4205	05/30/2013 06/27/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ADVANCED APOTHECARIES INC, FORT SMITH, AR - EIR, 483, CO RESP 1/12
2013-4206	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ANTIGEN LABORATORIES-COLUMBUS, COLUMBUS, OH - EIR, 483, CO RESP 6/12
2013-4207	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA, DECATUR, IL - EIR, 483, CO RESP 3/12
2013-4208	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA, COLUMBUS, OH - EIR, 483, CO RESP 8/12
2013-4209	05/30/2013 06/27/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, LAWRENCE, KS - EIR, 483, CO RESP 2/12
2013-4210	05/30/2013 06/27/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, ALBUQUERQUE, NM - EIR, 483, CO RESP 6/12
2013-4211	05/30/2013 06/27/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, PORTLAND, OR - EIR, 483, CO RESP 1/12
2013-4212	05/30/2013 06/27/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	DANIEL J MERENSTEIN MD, WASHINGTON, DC - EIR, 483, CO RESP 3/12
2013-4213	05/30/2013 06/27/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	DENNIS S RIFF MD, ANAHEIM, CA - EIR, 483, CO RESP 8/12
2013-4214	05/31/2013 06/28/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION - CORR, SUMMARIES RE REYNOLDS AMERICAN OR RJ REYNOLDS TOBACCO CO
2013-4215	05/31/2013	FDA/OMPT/CTP/OD/	Desmond Jenson	LIST OF SUBSTANTIAL EQUIVALENCE APPLICATIONS

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	06/28/2013		Tobacco Control Legal Consortium	SUBMITTED BY REYNOLDS AMERICAN OR RJ REYNOLDS TOBACCO CO (06/22/2009 - 05/29/2013)
2013-4216	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Valentine Elekta Inc.	K111106, K061140, K102650, ETC
2013-4217	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 04/30/2013 TO PRESENT
2013-4218	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joshua A. Malamud Hyman, Phelps & McNamara, P.C.	PS100006 - RESPONSE TO SECTION 522 REQUEST DATED 7/21/2010
2013-4219	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Carol Schmidt Seattle Genetics, Inc.	IBRUTINIB MANTLE CELL LYMPHOMA - BREAKTHROUGH THERAPY APPLICATION AND CORR
2013-4220	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Art Rankis Art Rankis	K973741
2013-4221	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mani Krishnan EMD Millipore Corporation	DMF 24055
2013-4222	05/31/2013 07/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Art Rankis Art Rankis	BK020043
2013-4223	05/31/2013 06/28/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF223200830014I MONTHLY REPORTS, ANNUAL REPORTS
2013-4224	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 074110 Arrastia, Capote & Phang, LLP	ANDA 074110
2013-4225	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 087639 Arrastia, Capote & Phang, LLP	ANDA 087639
2013-4226	05/31/2013 06/28/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDA 074106 Arrastia, Capote & Phang, LLP	ANDA 074106

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4227	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 087632 Arrastia, Capote & Phang, LLP	ANDA 087632
2013-4228	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8664812 8679576 8702172 ETC
2013-4229	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8663616 8709294 8724649 ETC
2013-4230	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Indeep Aulak Response Point of Care Inc.	K100130
2013-4231	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, SOURCE DOCUMENTS 8715487
2013-4232	05/31/2013 07/03/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Anne Myers Kaufman Dolowich Voluck LLP	SYNTHES USA - CORR WITH FDA RE FAILURE TO ABIDE BY CORPORATE INTEGRITY AGREEMENT
2013-4233	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Malamud Hyman, Phelps & McNamara, P.C.	NDA 021998 S002 - SBA
2013-4234	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE - 8697566 8746664
2013-4235	05/31/2013 06/28/2013	CVM/OCD/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Tom Amoss Tom amoss	AHC PRODUCTS - INSPECTIONS, ADVERSE EVENTS 2011 TO PRESENT
2013-4236	05/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	J.D. Webb	K112470

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	06/28/2013		The OrthoMedix Group, Inc.	
2013-4237	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16 MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE DOCUMENTS 8746477
2013-4238	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristine Kim Neurocrine Biosciences, Inc.	NDA 21894
2013-4239	05/31/2013 07/03/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Anne Myers Kaufman Dolowich Voluck LLP	SYNTHES USA - CORR RE WARNING LETTER (04/02/2012 - 05/29/2013)
2013-4240	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mani Krishnan EMD Millipore Corporation	DMF 3557, DMF 3561, DMF 9831 ETC
2013-4241	05/31/2013 07/03/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Anne Myers Kaufman Dolowich Voluck LLP	SYNTHES USA - CORR WITH FDA EXCLUDING MAUDE REPORTS RE SCREWS, GUIDEWIRES, DRILL BITS (04/01/2012 - 05/28/2013)
2013-4242	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	DIRECT REPORTS, MEDWATCH REPORTS, ANY SOURCE DOCUMENTS 8713701 8750425
2013-4243	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 087617 Arrastia, Capote & Phang, LLP	ANDA 087617
2013-4244	05/31/2013 06/28/2013	FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2013-N-0227 - COMMENTS TO DOCKET
2013-4245	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121710
2013-4246	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Whalen Hutton & Hutton Law Office	INDIVIDUAL RECS
2013-4247	05/31/2013	FDA/OMPT/CDER/GRP/DIDP/	ANDA 088856	ANDA 088856

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	06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arrastia, Capote & Phang, LLP	
2013-4248	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	THOMAS P VALET ESQ RHEINGOLD, VALET, ET AL	HEALTHCARE PROFESSIONAL SHEET, FDA ALERT - ORAL SODIUM PHOSPHATE (OSP) PRODUCTS FOR BOWEL CLEANSING
2013-4249	05/31/2013 06/28/2013	FDA/OO/OFBA/OAGS/	FRANK J CHILLI CENTURION RESEARCH SOLUTIONS	AQUILENT - TASK ORDER HHSF223201210959G AWARDED UNDER CONTRACT GS35F472G
2013-4250	05/31/2013 06/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS
2013-4251	05/31/2013 07/12/2013	FDA/OF/CFSAN/OCD/EOS/	RUBY E BURNER Keller and Heckman LLP	DAI-ICHI KOGYO SEIYAKU CO LTD - FCN 1257
2013-4252	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER ESQ WILSON SONSINI ET AL	PLAN B ONE-STEP (LEVONORGESTREL) TABS NDA 21-998/S002
2013-4253	05/31/2013 06/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	KIM THORSON Medical Products Laboratories, Inc.	VARNISHAMERICA - K040098
2013-4254	05/31/2013 06/28/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	MICHELLE POULK BURLESONS PURE HONEY	NATURE NATE'S HONEY, NORTH DALLAS HONEY CO, FRISCO, TX - WARNING LTRS, CORR, ORDERS, ETC 3/20/12 TO 5/31/13; CMLNT 125652
2013-4255	05/31/2013 09/17/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2013-4256	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PROJECT ON GOVERNMENT OVERSIGHT	DPV-I - PHARMACOVIGILANCE RVW 12/15/11
2013-4257	05/31/2013 06/28/2013	FDA/OF/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 0A4705
2013-4258	05/31/2013 06/28/2013	FDA/OF/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 9A4692

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2013-4259	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-4260	05/31/2013 06/28/2013	FDA/OF/CFSAN/OCD/EOS/	CHARLES CELESTE EAS CONSULTING GROUP LLC	FAP 1A4729
2013-4261	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	PANCREAS - AER
2013-4262	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	HYPERTENSION DRUG RECALLS
2013-4263	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY	NEUROLOGY RECALL MEDICATIONS
2013-4264	05/31/2013 06/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	MINI SENTINEL PRADAXA STUDY 2011
2013-4265	05/31/2013 06/28/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	JIM FANGMAN HILL ROM	SCM TRUE AIR TECHNOLOGIES LLC, LOUISVILLE, KY - 483
2013-4266	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/	NORMAN M. GOLDFARB JOURNAL OF CLINICAL RESEARCH BEST PRACTICES	QUESTIONS AND ANSWERS FDA PROVIDED THROUGH GCPQUESTIONS@OC.FDA.GOV 2012
2013-4267	05/31/2013 06/28/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	DAVE EISENHUT NORPAC FOODS	HHE 8452
2013-4268	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	HOLLIS 377055/D2205, ANTHONY .	DIABETES MEDICATIONS AER
2013-4269	05/31/2013 06/28/2013	FDA/OC/OES/DFOI/	JACK A. KRAMER WESTLAND KRAMER BENNETT PC	HEALTHCARE PROFESSIONAL SHETT 3/06; SCIENCE BACKGROUND PAPER 5/06; ALERT 12/11/08
2013-4270	05/31/2013 06/28/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	JOY J. LIU ROPES GRAY LLP	DENTAL EZ INC; RAMVAC DENTAL PRODUCTS INC; CUSTOM AIR - EIRS, 483S, MDRS, ETC 2008 TO 2013

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		FDA/OGROP/ORR/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/		
2013-4271	05/31/2013 06/28/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	HOOKE, BRIAN S	AUTISM & BIOPSY STUDY; IMMUNIZATIONS & DEVELOPMENT STUDY
2013-4272	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	STERLING IF SCREW EYELET & STERLING CROSS-PIN EYELET - K063584
2013-4273	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	LATANIA BLACK MEDTRONIC	STERLING INTERFERENCE SCREW HT & STERLING INTERFERENCE SCREW ST - K060253
2013-4274	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JEAN DOMENICO SANDOZ	OWEN MUNFORD, MARIETTA, GA - AUTOJECT II - CLEARANCE LTR
2013-4275	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	MARC CHAFETZ AMERICAN LAW PARTNERS	AVASTIN - RPTS OF OFF LABEL USE
2013-4276	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHRISTOPHER J GANSEN GANSEN LAW GROUP	ADVATE - HEPATITIS C AERS
2013-4277	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	SCOTT A HODES Scott A. Hodes, Attorney at Law	ICULSIG (PONATINIB) - AERS DETAILED RPT
2013-4278	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	MARC CHAFETZ AMERICAN LAW PARTNERS	ANGIOTENSIN RECEPTOR BLOCKERS (ARB) - RPTS
2013-4279	06/03/2013 07/01/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	HOLGER WEIS DEMEX INC	IND #39680 - RECS
2013-4280	06/03/2013	FDA/OMPT/CBER/OCOD/DDOM/	CHRISTOPHER J GANSEN	HEMOFIL (ANITHEMOPHILIC FACTOR HUMAN) - HEPATITIS

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	07/01/2013	ALFB/	GANSEN LAW GROUP	C VAERS
2013-4281	06/03/2013 07/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANOSHIMA HOSPITAL FOR SICK CHILDREN	COPAXONE (GLATIRAMER ACETATE) - ISRS 3035510, 3163637, 3151816, ETC
2013-4282	06/03/2013 07/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Doe J	ENOXAPARIN SODIUM - SPL #781-587-7466, SPL #740431 - TEST RESULTS
2013-4283	06/03/2013 07/01/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Lonza Biologics, Inc., Newington, NH
2013-4284	06/03/2013 07/01/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: ImmunoGen, Norwood, MA
2013-4285	06/03/2013 07/01/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Infinity Pharmaceuticals, Cambridge, MA
2013-4286	06/03/2013 07/01/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Lonza Group Ltd., Hopkinton, MA
2013-4287	06/03/2013 07/01/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Shire Human Genetic Therapies, Lexington, MA

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2013-4288	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Stryker Biotech, Hopkinton, MA
2013-4289	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Vertex Pharmaceuticals, Cambridge, MA
2013-4290	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Millenium (Takeda), Cambridge, MA
2013-4291	06/03/2013 07/01/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the releasable inspection reports, 483s, and the firms available correspondence from January 1 2012 to July 31 2012 for: Merrimack Pharmaceuticals Inc., Cambridge, MA
2013-4292	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088857 Arrastia, Capote & Phang, LLP	ANDA 088857
2013-4293	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088855 Arrastia, Capote & Phang, LLP	ANDA 088855
2013-4294	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 087616 Arrastia, Capote & Phang, LLP	ANDA 087616
2013-4295	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDA 088853 Arrastia, Capote & Phang, LLP	ANDA 088853
2013-4296	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Taylor Taylor, Sharon	LEVOQUIN - AERS

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2013-4297	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina M. Babos IPD ANALYTICS LLC	ANDA 201-578 - EFFECTIVE APPROVAL LETTER
2013-4298	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Todd West-Ward Pharmaceutical Corp.	GETZ PHARMA RESEARCH PVT, LTD, INDIA - 483 MAY 2013
2013-4299	06/03/2013 07/01/2013	CVM/OCD/	B-TERA B-TERA	IFA-11-317
2013-4300	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Constantine Panagotacos Dunn & Panagotacos LLP	CITANEST PLAIN DENTAL 4% - WARNINGS, TESTING, DANGERS
2013-4301	06/03/2013 07/01/2013	FDA/OF/CFSAN/OCD/EOS/	Jeff Goehring YOUNG & THOMPSON	CHLORELLA - SUBMISSION FOR APPROVAL AS FOOD SUBSTANCE
2013-4302	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Todd West-Ward Pharmaceutical Corp.	CIPLA, LTD, MUMBIA, INDIA - 483 MAY 2013
2013-4303	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christina Patullo Long Pharmaceuticals, LLC	NDA 013960 - SBA
2013-4304	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LuLu HEC PARIS	NDA 018780 - APPROVAL RECS
2013-4305	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Bradbury SUMMIT MEDICAL LTD	K071520
2013-4306	06/03/2013	FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch	VICTRELIS, BOCEPREVIR - AERS

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2013-4307	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sean Cho TaoNetworks Int'l., Inc.	K121700
2013-4308	06/03/2013 07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gil Shapira G.N.S neoLaser Ltd	K120938
2013-4309	06/03/2013 07/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 5/1-31/2013
2013-4310	06/03/2013 07/01/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CLOSED FOIA REQUESTS (5/1-31/2013)
2013-4311	06/03/2013 07/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	INCIVEK, TELAPREVIR - AERS
2013-4312	06/04/2013 07/02/2013	FDA/OF/CFSAN/OCD/EOS/	DAN FREEMAN WELLS ANDERSON & RACE LLC	TABZ TEA CLEAN - CMPLNTS, CORR, NOTES, ETC
2013-4313	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN S BAKER LIGHTFOOT FRANKLIN & WHITE LLC	TESTOPEL - ISR 8178925
2013-4314	06/04/2013 07/02/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	ROSE H GOLDMAN MD MPH HARVARD SCHOOL OF PUBLICH HEALTH	THALLIUM IN NALTREXONE - RECS
2013-4315	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER ESQ WILSON SONSINI ET AL	BANNER PHARMACAPS - DUTASTERIDE CAPS ANDA 200-899 FINAL APRVL LTR
2013-4316	06/04/2013 07/02/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	HOLLY J BAYNE BAYNE & ASSOCIATES	NESTLE HEALTHCARE NUTRITION - BOOST KID ESSENTIALS NUTRITIONALLY COMPLETE DRINK MEDICAL FOOD WARNING LTR 12/3/09; BIOENERGY INC - CORVALEN M, CORVALEN, CORVALEN CHEWABLE WAFER CORR, MEMOS, TRANS, ETC
2013-4317	06/04/2013	FDA/OC/OES/DFOI/	RAFE LEWIS	ABIOMED INC, MEDICARE ADMINISTRATIVE

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	07/02/2013		NORTH RUN CAPITAL LP	CONTRACTORS, HHS - IMPELLA CORR
2013-4318	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HATTON 1519223, ROLAND	BOEHRINGER-INGELHEIM - DOPAMINE AGONISTS, MIRAPEX (PRAMIPEXOLE HCL) AERS, CORR 1997 TO 2005
2013-4319	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GREGORY H LEVINE ROPES & GRAY LLP	OMS721 - CMLPNT LTRS SUBMITTED TO THE OFFICE OF PRESCRIPTION DRUG PROMOTION 4/8/13, 4/22/13
2013-4320	06/04/2013 07/02/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAMES R JARROW BAKER STERCHI COWDEN & RICE LLC	BDI - CARDIOGEN-82 NDA 19-414 INVESTIGATION, VIOLATIONS, CORR, ETC 3/1/11 TO PRESENT
2013-4321	06/04/2013 07/02/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 4/1-30/13
2013-4322	06/04/2013 07/02/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	KOSNETT, MICHAEL J	LIFE VANTAGE - PROTANDIM RECALL RECS
2013-4323	06/04/2013 07/02/2013	FDA/OC/OES/DDM/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 2003P-0064
2013-4324	06/05/2013 07/03/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARIA K. TOUGAS SCOTT & SCOTT	PHILLIPS - LIFELINE MEDICAL ALERT DVC CMLPNTS
2013-4325	06/05/2013 07/03/2013	FDA/OMPT/CTP/OD/	JOE MAPOTHER TOBACCO JOURNAL INTERNATIONAL	NEW APPLICATIONS FILED IN CTP
2013-4326	06/05/2013 07/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HENNING, CHARLES	TAMSULOSIN HCL - AER
2013-4327	06/05/2013 07/03/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING.ORG	VERMA NUTRITION CO, SCOTTSDALE, AZ - VERVE; NEXT CMLPNTS

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2013-4328	06/05/2013 07/03/2013	FDA/OC/OES/DFOI/	HOLZERLAND, WILLIAM	SECURITY CAMERA FOOTAGE AT FDA
2013-4329	06/05/2013 07/03/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	THOMAS FAHEY NATIONAL CORPORATE RESEARCH	ABILIFY - BRISTOL MYERS SQUIBB COMM, EFFICACY, LBLG, APRVL 2002 TO 2007
2013-4330	06/05/2013 07/03/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	JOSHUA TURNER GOLDWATER INSTITUTE	APPLICTIONS FOR COMPASSIONATE USE 1/05 TO PRESENT
2013-4331	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	VALLEY HEALTH INSWTITUTIONAL REVIEW BOARD, WINCHESTER, VA - EIRS, 483S, CO RESP 1/29/13-2/01/13
2013-4332	06/06/2013 08/07/2013	FDA/OGROP/ORAPPA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPPA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	JOSE JOSEPH-VEMPILLY MD, FRESNO, CA - EIRS, 483S, CO RESP 9/13/12-10/11/12
2013-4333	06/06/2013 07/05/2013	FDA/OGROP/ORAPPA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORAPPA-FO/LOS- DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	INNOVATIVE MED INC, IRVINE, CA - EIRS, 483S, CO RESP 10/03-09/12
2013-4334	06/06/2013 07/05/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CMI COSMETIC MANUFACTURERS INC, CONCORD, ONTARIO, CANADA - EIRS, 483S, CO RESP 10/12
2013-4335	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	V-SAB MEDICAL LABS INC, CORNELIUS, NC - EIRS, 483S, CO RESP 5/22/12-6/20/12
2013-4336	06/06/2013	FDA/OGROP/ORACE-FO/BLT-	WALTER E CHALKLEY	LONZA WALKERVILLE, WALKERVILLE, MD - EIRS, 483S, CO

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	07/05/2013	DO/BLT-CB/	THOMSON REUTERS	RESP 12/11
2013-4337	06/06/2013 07/05/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	IMPAX LABS, HAYWARD, CA - EIRS, 483S, CO RESP 3/13
2013-4338	06/06/2013 07/05/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	ACORDA THERAPEUTICS, HAWTHORNE, NY - EIRS, 483S, CO RESP 8/15/11-09/09/11
2013-4339	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WAWLTER E CHALKLEY THOMSON REUTERS	CATALENT PHARMA SOLUTIONS, MORRISVILLE, NC - EIRS, 483S, CO RESP 2/13
2013-4340	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDTRONIC SPINAL & BIOLOGICS, WEXFORD, PA - EIRS, 483S, CO RESP 01/23/12
2013-4341	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LIFESOURCE-UPPER MIDWEST OPO, SAINT PAUL, MN - EIRS, 483S, CO RESP 01/24/12
2013-4342	06/06/2013 07/05/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXOSMITHKLINE CONSUMER HEALTHCARE, LP, CLIFTON, NJ - EIRS, 483S, CO RESP 01/09/12
2013-4343	06/06/2013 07/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	GENZYME FLANDERS NV, GEEL, BELGIUM - EIRS, 483S, CO RESP 01/24/12
2013-4344	06/06/2013 07/05/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	MICHAEL DESANTIS, HICKORY, NC - EIRS, 483S, CO RESP 01/05/12
2013-4345	06/06/2013 09/10/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMGEN INC, BOULDER, CO - EIRS, 483S, CO RESP 01/06/12
2013-4346	06/06/2013 07/05/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMGEN INC, WEST GREENWICH, RI - EIRS, 483S, CO RESP 01/20/12
2013-4347	06/06/2013 07/25/2013	FDA/OGROP/ORAP/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLURE LABORATORIES, INC, HAYWARD, CA - EIRS, 483S, CO RESP 01/12/12
2013-4348	06/06/2013 07/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER BIOSCIENCE, VIENNA, AUSTRIA - EIRS, 483S, CO RESP 01/19/12
2013-4349	06/06/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, BAXTER AG, WIEN, AUSTRIA - EIRS, 483S, CO RESP 01/31/12

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2013-4350	06/06/2013 07/05/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO RAD LABORATORIES INC, WOODINVILLE, WA - EIRS, 483S, CO RESP 01/31/12
2013-4351	06/06/2013 07/05/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAPITAL HEALTH, TRENTON, NJ - EIRS, 483S, CO RESP 1/27/12
2013-4352	06/06/2013 07/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXOSMITHKLINE CONSUMER HEALTHCARE (GLAXOSMITHKLINE), AIKEN, SC - EIRS, 483S, CO RESP 01/27/12
2013-4353	06/06/2013 07/05/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	GRAFT SOURCE LLC, GRAPEVINE, TX - EIRS, 483S, CO RESP 01/11/12
2013-4354	06/06/2013 07/05/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	HACKENSACK UNIVERSITY MEDICAL CENTER, BLOOD BANK, HACKENSACK, NJ - EIRS, 483S, CO RESP 01/24/12
2013-4355	06/06/2013 07/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	WALTER E CHALKLEY THOMSON REUTERS	HUSASHU PHARMACEUTICAL CORP, SHIJAZHUANG, CHINA - EIRS, 483S, CO RESP 01/12/12
2013-4356	06/06/2013 07/05/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	OCTAPharma PLASMA INC, PETERSBURG, VA - EIRS, 483S, CO RESP 01/24/12
2013-4357	06/06/2013 07/05/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	OCTAPharma PLASMA INC, KALAMAZOO, MI - EIRS, 483S, CO 01/23/12
2013-4358	06/06/2013 07/05/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMERICAN RED CROSS BLOOD SERVICES TENNESSEE VALLEY REGION, NASHVILLE, TN - EIRS, 483S, CO RESP 01/05/12
2013-4359	06/06/2013 07/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BOEHRINGER-INGELHEIM PHARMA GMBH, INGELHEIM AM RHEIN, GERMANY - EIRS, 483S, CO RESP 11/05-12/12

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2013-4360	06/06/2013 07/05/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACELL INC, COLUMBIA, MD - EIRS, 483S, CO RESP 11/28/12-12/20/12
2013-4361	06/07/2013 07/08/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Paul Blackburn Cubist Pharmaceuticals	PALM SPRINGS RESEARCH INSTITUTE, INC, HIALEAH, FL - EIR, 483, RESPONSE 6/6/2011
2013-4362	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Paul Blackburn Cubist Pharmaceuticals	CHRISTOPHER J LUCASTI DO, SOMERS POINT, NJ - EIR, 483, RESPONSES (10/15/2007 - 12/30/2007)
2013-4363	06/07/2013 07/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Blackburn Cubist Pharmaceuticals	MOHAMED BIDAIR, MD, LA MESA, CA - EIR, 483, RESPONSES (03/16/2011 - 03/16/2011)
2013-4364	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Paul Blackburn Cubist Pharmaceuticals	CHRISTIAN G SCHROCK, MD, MINNEAPOLIS, MN - EIR, 483, RESPONSES (03/14/2007 - 12/01/2007)
2013-4365	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Paul Blackburn Cubist Pharmaceuticals	CHRISTOPHER J LUCASTI, SOMERS POINT, NJ - EIR, 483, RESPONSES (04/11/2007 - 04/11/2007)
2013-4366	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Blackburn Cubist Pharmaceuticals	VERONIKA B POPOVA, MD, ST PETERSBURG, RUSSIA - EIR, 483, RESPONSES (02/18/2008 - 12/01/2008)
2013-4367	06/07/2013 07/08/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Paul Blackburn Cubist Pharmaceuticals	AHMAD A HAIDAR, MD, PICAYUNE, MS - EIR, 483, RESPONSES (04/04/2005 - 04/04/2005)
2013-4368	06/07/2013 07/08/2013	ORA/ ORA/	Melissa Hipolit WJHL-TV	COMPOUNDING PHARMACIES IN TENNESSEE - INSPECTION REPORTS (05/30/2012 - 05/30/2013)
2013-4369	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Eric Young Kessler Topaz Meltzer & Check, LLP	ST JUDE MEDICAL - INSPECTION RECS RE LEADS (09/01/2009 - 12/31/2009)
2013-4370	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael P. Manapol, Esq. Law Offices of Brian D. Witzer, Inc.	EOSINOPHILIA - AERS

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2013-4371	06/07/2013 07/08/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Penny Northcutt/REGSolutions, LLC REGSolutions, LLC	BLANCHARD CONTACT LENS INC, NH - EIR JUNE 2011
2013-4372	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Derek Auito MCKENNA LONG & ALDRIDGE LLP	LABORATORIOS ANDROMACO SA, SANTIAGO, CHILE - REGISTRATION WITH DECRS DATABASE (01/01/2010 - 05/01/2013)
2013-4373	06/07/2013 07/08/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	MERCK & CO - COMPLIANCE RECORDS FOR IMPORTS INTO THE US 2012-2013
2013-4374	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Marc C. Sanchez, Esq. Contract In-House Counsel and Consultants, LLC	COMFREY - AERS, SCIENTIFIC DATA, CLINICAL STUDIES RE ADVISORY
2013-4375	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Duloxetine for major depressive disorder The Nordic Cochrane Centre	DULOXETINE WITH THE INDICATION DEPRESSIVE DISORDER - FULL TRIAL PROTOCOLS, AMENDMENTS, REPORTS ETC
2013-4376	06/07/2013 07/31/2013	FDA/OMPT/CTP/OD/ FDA/OC/OES/	Yltzchak Jacobovitz CAPSTONE LLC	CORR BETWEEN CTP AND OMB, MEETINGS, MENTHOL CIGARETTE RECS (01/01/2011 - 05/31/2013)
2013-4377	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	LM Hanley Navilyst Medical, Inc	LETTER TO MANUFACTURERS OF 510K CLEARANCES FOR PROCEDURE DXT (07/01/2012 - 07/15/2012)
2013-4378	06/07/2013 07/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	UNTITLED LETTER ISSUED 2008 RE ASSIGNMENT NUMBER 808885
2013-4379	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess B. Burgess	LETTER TO CDER EXEC SEC FROM L BALL RE COMPLAINT 1639

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4380	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Tillino Patrick Tallino	K123769
2013-4381	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tracy O'Neill Tracy O'Neill	XARELTO - AERS
2013-4382	06/07/2013 07/08/2013	CVM/OCD/	Gaurav Shah BioResource International,Inc	GM FEED ENZYMES EXPRESSED IN GENETICALLY MODIFIED EXPRESSION SYSTEMS - SAFETY INFORMATION
2013-4383	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Tallino Patrick Tallino	K113621
2013-4384	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shaheen Wirk Palkon Capital Management	NCT00708201 - STUDY RESULTS
2013-4385	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K000515
2013-4386	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christine Nichols Boston Biomedical Associates	K873643, K840532
2013-4387	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K070897
2013-4388	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K082629
2013-4389	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Perkins AgaMatrix, Inc	K121291
2013-4390	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K883149
2013-4391	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K111717
2013-4392	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K883149
2013-4393	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K885306

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2013-4394	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Brooks Microbiotix, Inc.	NDA 050347 - SBA
2013-4395	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Aftab Ahmad Neurowave Medical Technology	K020020, K040512
2013-4396	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Karin Desjardins COVIDIEN	K993691
2013-4397	06/07/2013 07/08/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Jason Lam New Horizon Enterprises Ltd.	ENTRY NUMBER D52-9005145-2
2013-4398	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Esther Farber Labaton Sucharow, LLP	2010-3944, 2012-6036
2013-4399	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Kumamoto HelixIP LLP	LAZANDA - FAERS
2013-4400	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Stephen Roos ASE Direct Inc.	PCARD HOLDERS
2013-4401	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ian Marsden CONSUMER	K123237
2013-4402	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ian Marsden CONSUMER	K120257
2013-4403	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marge Walls-Walker Cook Medical	K112454
2013-4404	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joanna Veres ClearView Diagnostics Inc.	K050846
2013-4405	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Joy Flynn flynn, joy	AVANTOR, PARIS, KY - EIR (01/02/2012 - 06/06/2013)
2013-4406	06/07/2013 07/08/2013	FDA/OF/CFSAN/OCD/EOS/	Amy Shipley The Fort Lauderdale Sun Sentinel	DRIVEN SPORTS CRAZE, GASPARI NUTRTION DETONATE - ADVERSE EVENTS, COMPLAINTS, WARNING LETTERS

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2013-4407	06/07/2013 07/08/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Kimberly D. Goodman Cooperstein, Esquire Murray, Kelly & Bertrand, P.C.	PALLIMED SOLUTIONS, INC, WOBURN, MA - COMPLAINT 132017, PUBLIC RECS
2013-4408	06/07/2013 07/08/2013	CVM/OCD/ ORA/ ORA/	Julie Putnam NBC Bay Area News (KNTV)	PET TREAT COMPLAINTS (01/01/2013 - 06/04/2013)
2013-4409	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anthony Castellazzo AMICUS THERAPEUTICS	BOEHRINGER INGELHEIM, RHEIN, GERMANY - EIR (11/05/2012 - 11/12/2012)
2013-4410	06/07/2013 07/08/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Caron McEWan Mountain Country Foods	SAMPLE RESULTS - MOUNTAIN COUNTRY FOODS, SPANISH FORK, UT
2013-4411	06/07/2013 07/08/2013	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	Peter Spaulding Peter Spaulding	FDA CORR WITH JEFFREY LIEBERMAN, SARAH "HOLLY" LISANBY, JAMES H. SCULLY JR (01/01/2008 - 06/03/2013)
2013-4412	06/07/2013 07/08/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Andres Cabrera Grunenthal LatAm	MALLINCKRODT, RALEIGH, NC - 483, EIR (06/01/2009 - 06/03/2013)
2013-4413	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott Talbot Gavis Pharmaceuticals, LLC	HOSPIRA HEALTHCARE INDIA PVT LTD - 483 (10/03/2012 - 10/10/2012)
2013-4414	06/07/2013 07/08/2013	ORA/ORM/ ORA/ORM/	b. burgess BURGESS, BERNIE	LIST OF INSPECTIONS CONDUCTED BY LOS ANGELES DISTRICT IN FY 2006
2013-4415	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael S. Sawaya Altaire Pharmaceuticals, Inc.	NDA 018299
2013-4416	06/07/2013 07/10/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Brad D Hewett The Mike Kelly Law Group	RESPIRONICS, INC SMARTMONITOR2
2013-4417	06/07/2013 07/30/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	David Mangione Govzilla, Inc.	BAXTER PHARMACEUTICAL SOLUTIONS LLC, BLOOMINGTON, IN - EIR, 483 (05/10/2013 - 05/10/2013)

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2013-4418	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	WOCKHARDT INDIA FACILITIES - 483 (12/17/2010 - 02/28/2012)
2013-4419	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gloukhova Svetlana AbbVie Inc	915 REVIEW OF FINGOLIMOD
2013-4420	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashley Yeager The Simon Law Firm	BENTYL - AERS, CASE REPORTS 6124897, 6534658
2013-4421	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dan Himmelfarb Mayer Brown LLP	TESTOSTERONE - APPROVAL RECS
2013-4422	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Blake Goodner Bridger Corporation	GILEAD SCIENCES, FOSTER CITY, CA - 483, WARNING LETTERS, RESPONSE LETTERS (01/01/2012 TO PRESENT)
2013-4423	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc	ICLUSIG - AERS
2013-4424	06/07/2013 07/08/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Michael R. McCann Michael R. McCann, P.A.	COMPLAINT 130549
2013-4425	06/07/2013 07/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Patti Krofft Pettit Kohn Ingrassia & Lutz	NATIONAL VITAMIN COMPANY, INC - TESTING RECS
2013-4426	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Larry Hagerman HAGERMAN INFORMATION SERVICES	BOEHRINGER INGELHEIM PHARMA GMBH & CO - CDER HHE REQUEST AND CONSULT
2013-4427	06/07/2013	FDA/OMPT/CDER/GRP/DIDP/	Geoffrey May	NCT00140179 - DATA ANALYSIS, STUDY RESULTS

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	07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	May, Geoffrey	
2013-4428	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kip Nelson SMITH MOORE LEATHERWOOD LLP	NESHER PHARMACEUTICALS (USA) LLC - 483, EIR, FIELD REPORT ETC
2013-4429	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lori Hays Merz Aesthetics, Inc.	ANTEIS SA, PLAN-LES-OATES - EIR 2/5/13
2013-4430	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Angela Birchall Bio Products Laboratory Limited	BIO PRODUUCTS LABORATORY LTD, ELSTREE, UK - EIR 6/13/11, ADVERSE EVENTS
2013-4431	06/07/2013 07/08/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BioPharm Insight	BLA ACCEPTED FOR REVIEW, COMPLETE RESPONSE LETTERS FOR CMC RELATED ISSUES, NAMES AND INDICATIONS OF BIOLOGICS, ETC
2013-4432	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 5/27/2013 to 5/31/2013
2013-4433	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kathrin Simmons Kathrin Simmons	K895365
2013-4434	06/07/2013 07/08/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Ilona W Surick EISAI INC	ESAI, WOODCLIFF LAKE, NJ - EIR (01/01/2013 - 02/25/2013)
2013-4435	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	FOIA REQUESTS RE RANBAXY DATA INTEGRITY, CGMP
2013-4436	06/07/2013 07/08/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Rachel Johnson FOI Services, Inc.	RANBAXY, GLOVERSVILLE, NY - EIR, 483, RESPONSES ETC 01/01/04 TO PRESENT

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2013-4437	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	RANBAXY, INDIA - EIR, 483, RESPONSES ETC
2013-4438	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Timothy Bassett Pura Vida Investments	JUXTAPID - AERS
2013-4439	06/07/2013 07/08/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-4440	06/07/2013 07/08/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDA NEWS	MEDICAL DVC, PHARMACEUTICAL, BIOLOGIC FACILITIES - 483S 5/13
2013-4441	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COOPER 328257, JACK .	DICCYLOMINE; KETAMINE; HALDOL; BENEDRYL - AER
2013-4442	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PERLMUTTER, SUZY	BOTOX AER
2013-4443	06/07/2013 07/08/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	JOHN VARONE ROYAL FOOD IMPORT CORPORATION	ENTRY NO E5R-1009888-2
2013-4444	06/07/2013 07/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARILYNN WHITNEY COVINGTON & BURLING LLP	CDRH UNTITLED LTRS SINCE 1/12
2013-4445	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH MEDICATION ERRORS 5/1-31/13
2013-4446	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SARI E. KOLATCH COHEN TAUBER ET AL	SHIONOGI PHARMA INC - 483, EIR 1/30 TO 2/8/12

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		FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/		
2013-4447	06/07/2013 07/08/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	DOROTHY A O'BRIEN ATTY AT LAW PLC	ARCHER DANIELS MIDLAND CO, CLINTON, IA - EIR 2009 TO PRESENT
2013-4448	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JASON T. SAYERS VENABLE LLP	PHENYTOIN SODIUM ANDA 84-307 - LBLG 1/00
2013-4449	06/07/2013 07/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHLEEN S. HARDWAY VENABLE LLP	BEDFORDS - KETOROLAC TROMETHAMINE ANDA 75-222 - LBLG SINCE 1/11; HOSPIRA - KETROLAC TROMETHAMINE ANDA 74-801 - LBLG SINCE 1/97
2013-4450	06/10/2013 07/09/2013	ORA/ ORA/	Katrina Reiling Parexel International	MP143 COMPUTER AIDED INSPECTIONS - ORA U COURSE MATERIALS
2013-4451	06/10/2013 07/09/2013	ORA/ ORA/	Katrina Reiling Parexel International	DV201 BASIC MEDICAL DEVICE - ORA U COURSE MATERIALS
2013-4452	06/10/2013 07/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Livoti BioPharm Insight	NUMBER OF NDAS ACCEPTED FOR REVIEW, NUMBER OF COMPLETE RESPONSE LETTERS RE CMC ISSUES, NAMES AND INDICATIONS OF DRUGS, ETC
2013-4453	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Flock Flock, Andrew J	BUDEPRION XL 300 MG - BIOEQUIVALENCE STUDY
2013-4454	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shirley Francis- Fraser SHIRLEY T ATTY	EXELON NDA 022083 SUPP 016 - REVIEW RECS
2013-4455	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Jeffries Boston Scientific Neuromodulation	MAUDE DATA - FIELD F10 PATIENT PROBLEM CODES
2013-4456	06/10/2013	ORA/	Katrina Reiling	DG201BASIC DRUG SCHOOL - ORA U COURSE MATERIALS

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	07/09/2013	ORA/	Parexel International	
2013-4457	06/10/2013	ORA/	Rachel Johnson	ORA U COURSE MATERIALS - DV303, DG307
	07/09/2013	ORA/	FOI Services, Inc.	
2013-4458	06/10/2013	FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta	ANDA 091563 - SBA
	07/09/2013	FDA/OMPT/CDER/GRP/DIDP/	Micro Labs USA, Inc	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-4459	06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joel Barr	K950899, K950898, K950897
	07/09/2013		Stericycle, Inc.	
2013-4460	06/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Jim Cassi, VP QA	RESMED CORPORATION - EIR (02/02/2009 - 02/27/2009)
	07/09/2013		ResMed Corporation	
2013-4461	06/10/2013	ORA/OE/	Jacob Harris	FOOD RECALL DATA
	07/09/2013	ORA/OE/	THE NEW YORK TIMES	
2013-4462	06/10/2013	FDA/OMPT/CTP/OD/	Rachel Johnson	TOTAL NUMBER OF SUBSTANTIAL EQUIVALENCE ORDERS UNDER FSPTCA, IDENTITY OF PRODUCTS
	07/09/2013		FOI Services, Inc.	
2013-4463	06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Daan De Coster	BECLOMETASONE INHALERS IN COPD - TRIALS USED TO SUPPORT UNSUCCESSFUL APPLICATIONS (01/01/1970 - 01/01/2006)
	07/09/2013		University College London and Cochrane Collaboration	
2013-4464	06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Daan De Coster	BECLOMETASONE - TRIALS USED TO SUPPORT UNSUCCESSFUL APPLICATIONS (01/01/1970 - 01/01/2006)
	07/09/2013	FDA/OMPT/CDER/GRP/DIDP/	University College London and Cochrane Collaboration	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-4465	06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kelly Rowan	ST JUDE RIATA LEADS - PMA, SUPPLEMENT, CORR ETC
	07/09/2013		Sitlinger, McGlinchy & Theiler	
2013-4466	06/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Evan Luxon	K110518
	07/09/2013		TheraNova LLC	
2013-4467	06/10/2013	ORA/	Katrina Reiling	MP143 COMPUTER AIDED INSPECTIONS, DV201 BASIC MEDICAL DEVICE, DG201 BASIC DRUG SCHOOL - ORA U COURSE MATERIALS
	07/09/2013	ORA/	Parexel International	
2013-4468	06/10/2013	FDA/OF/CFSAN/OCD/EOS/	Joshua Valero	MONSTER BEVERAGE CORPORATION - NUTRIENT CONTENT CLAIM PETITIONS LAST FIVE YEARS
	07/09/2013		Capstone Law APC	
2013-4469	06/10/2013	FDA/OMPT/CDER/GRP/DIDP/	Susan Zolnier	DIOSYNTH FRANCE SA, EURAGNY-SUR-EPTE - EIR (01/02/2013 - 05/31/2013)
	07/09/2013	FDA/OMPT/CDER/GRP/DIDP/	MannKind Corporation	

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-4470	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Wezowski Leydig, Voit & Mayer LTD	NDA 17716, 18217, 17576 ETC - CMC
2013-4471	06/10/2013 07/09/2013	FDA/OF/CFSAN/OCD/EOS/	Joshua Valero Capstone Law APC	HANSEN NATURAL CORPORATION - NUTRIENT CONTENT CLAIM PETITIONS LAST FIVE YEARS
2013-4472	06/10/2013 07/09/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Jason A Dean Hulsey Oliver & Mahar, LLP	JARCHEM INDUSTRIES INC - CORR, REGISTRATIONS, INSPECTIONS
2013-4473	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	MACROLANE - PRE-IDE, IDE, PMA ETC
2013-4474	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran & Associates	JUVEDERM - PRE-IDE, IDE, PMA, ETC
2013-4475	06/10/2013 07/09/2013	FDA/OC/OES/ FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	Sara D. Avila Avila, Sara D	GMO - CITIZEN PETITION, REFERRALS
2013-4476	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fergus E McKiernan MARSHFIELD CLINIC PEDIATRICS DEPT	PROLIA - AERS
2013-4477	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bao Tran Tran & Associates	RESTYLANE INJECTABLE GEL - PRE-IDE, IDE, PMA ETC
2013-4478	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	BTran Tran & Associates	K110318
2013-4479	06/10/2013 07/09/2013	CVM/OCD/	Bryndis Stefansdottir Isteka ehf.	ITSEKA EHF - EIR (06/20/2011 - 05/28/2013)
2013-4480	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-4481	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ ORA/OCI/ ORA/OCI/	Rachel Johnson FOI Services, Inc.	USA V. RANBAXY RECS, CONSENT DECREE
2013-4482	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	RANBAXY - DATA INTEGRITY EXPERT
2013-4483	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	PRE-SUBMISSION AUDITS OF APPLICATIONS OF RANBAXY APPPLICATIONS
2013-4484	06/10/2013 07/09/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	COMMUNICATIONS BETWEEN FDA AND DINESH THAKUR RE RANBAXY
2013-4485	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ ORA/OCI/ ORA/OCI/	Rachel Johnson FOI Services, Inc.	RECS RE THAKUR V. RANBAXY
2013-4486	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	USA V. RANBAXY USA - PLEA AGREEMENT, PLEA SUPPLEMENT

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		OC/OCC/ ORA/OCI/ ORA/OCI/		
2013-4487	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	Rachel Johnson FOI Services, Inc.	RANBAXY - RECS RE 9/16/08 IMPORT ALERT
2013-4488	06/10/2013 07/09/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ ORA/OCI/ ORA/OCI/	Rachel Johnson FOI Services, Inc.	RANBAXY - APPLICATION INTEGRITY POLICY, CAOP
2013-4489	06/10/2013 07/09/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	RANBAXY - MEDIA FOIA REQUESTS
2013-4490	06/10/2013 07/09/2013	CVM/OCD/	JENNIFER VRIONIS, MS KINDRED BIOSCIENCES NC	AYERST LABORATORIES INC, NEW YORK, NY - PRIMIDONE TABS NADA 009-392 DRUG EFFICACY STUDY IMPLEMENTATION (DESI) RVW RPT
2013-4491	06/10/2013 07/09/2013	CVM/OCD/	JENNIFER VRIONIS, MS KINDRED BIOSCIENCES NC	FORT DODGE LABORATORIES INC, FORT DODGE, IA - MYLEPSIN TABS NADA 010-091 DRUG EFFICACY STUDY IMPLEMENTATION (DESI) RVW RPT
2013-4492	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM REYNOLDS FIRST I INVESTIGASTIONS	U&I CORPORATION , SOUTH KOREA -OPTIMA SPINAL PEDICLE FIXATION; ZS SPINAL FIXATION SYS; DYNESY SEST SCREWS, ETC MDRS
2013-4493	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	WILLIAM REYNOLDS FIRST I INVESTIGASTIONS	U&I CORP - OPTIMA SPINAL SYS K024096
2013-4494	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	MONIKA BHATT HODGSON RUSS LLP	AUTOMATED OPHTHALMIC INC - SOFTIPS K992998, ACCUTOME ULTRASOUND INC - ACCUPEN K083377
2013-4495	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KIM HENDERSON SANOFI PASTEUR	EBEWE PHARMA GES MBH NFG UNTERACH AM ATTERSEE, AUSTRIA - 483S 10/15-23/12

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4496	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	STOBAUGH, A DERRICK	TNF-A INIBITORS -ISRS 4035003, 5668246, 5850508, ETC
2013-4497	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	T CHRISTIAN MILLER PROPUBLICA	MCNEIL CONSUMER HEALTHCARE - 7147034, 7380883, 3782721 ISRS ETC
2013-4498	06/10/2013 07/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	BONNIE BASHAM CAPITAL IDEAS	MEDAFOR INC - ARISTA AH ABSORABLE HEMOSTAT P050038 IX SUMMARY PRE-CLNCL STUDIES
2013-4499	06/10/2013 07/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S WALKER SEATTLE GENETICS INC	ADCETRIS (BRENWTUXIMAB VEDOTIN) - AERS 9/1/12 TO 5/31/13
2013-4500	06/10/2013 07/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	THOMAS F SPENADER	VI-JON LABORATORIES INC - EIRS, 483S, WARNING LTRS 4/07 TO PRESENT
2013-4501	06/10/2013 07/09/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BOB FRANKSON LEVLLAD LLC	LEVLLAD LLC, CHATSWORTH, CA - EIRS 9/2-9/10
2013-4502	06/10/2013 07/09/2013	FDA/OC/OES/DDM/ FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHERYL B SHAPIRO CLEARY GOTTLIEB STEEN ET AL	ENDOCRINOLOGIC & METABOLIC DRUGS A/C 6/13-07 - RIMONABANT NDA 21-888 REC, RVWS, APRVL, ETC
2013-4503	06/10/2013 07/09/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	AMY BOJIE LI FUZHOU GOLDEN BANYAN FOODSTUFFS CO LTD	ENTRY ES6-4014665-1/8/1 - DETENTION NOTICE
2013-4504	06/10/2013 07/09/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	Erika Knudsen Center for Science in the Public Interest	CONSUMER COMPLAINTS. REQUESTS FOR ENFORCEMENT ACTION FOR MISBRANDED PRODUCTS 06/01/2008 UNDER 402, 403 OF THE FDCA, 21 CFR PART 101

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2013-4505	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	CORR RE 02/25/2009 MEMO BY JANET WOODCOCK RE RANBAXY DATA INTEGRITY
2013-4506	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bernard Bedor spinal resources inc	CAPTIVA SPINE, JUPITER, FL - REPACKAGING, RELABELING
2013-4507	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	WOCKHART LTD, AURANGABAD, WALUG - 483, CORR (01/01/2010 - 06/07/2013)
2013-4508	06/11/2013 07/10/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alaska Burr NORTH RUN CAPITAL LP	WOCKHARDT - 483, CORR (01/01/2010 - 06/07/2013)
2013-4509	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	FACTS 808885 - FINANCIAL RECS
2013-4510	06/11/2013 07/10/2013	FDA/OC/OES/DFOI/	b.burgess BURGESS, BERNIE	DFOI CORR WITH DIANE F WALKER RE 2007-3879
2013-4511	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess B. Burgess	FACTS 808885 - FMD 145 LETTER
2013-4512	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	EI ENDORSEMENT FOR FACTS 808885
2013-4513	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Andrew Buckler vascuVis Inc.	K043111
2013-4514	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Buckler vascuVis Inc.	K073156
2013-4515	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amanda Goodwin EISAI INC	TYSABRI BLA 125104 - SBA

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2013-4516	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 40091
2013-4517	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jerry Lee True Diagnostics	K023642
2013-4518	06/11/2013 07/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 074460 - SBA
2013-4519	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Buckler vascuVis Inc.	K082607
2013-4520	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrew Buckler vascuVis Inc.	K071331
2013-4521	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN COLQUITT Standly & Hamilton, LLP	K050646, K051986, K052390, ETC
2013-4522	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K042598, K043227, K043560, ETC
2013-4523	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K030597, K032269, K032269, ETC
2013-4524	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K082072, K082300, K082624, ETC
2013-4525	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K072083, K072423, K072832, ETC
2013-4526	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K083573, K083843, K090877, ETC
2013-4527	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K092812, K100676, K101423, ETC
2013-4528	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K111039, K120689
2013-4529	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K011978, K013248, K020872, ETC
2013-4530	06/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT	K961413, K982347, K983853, ETC

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	07/10/2013		Standly & Hamilton, LLP	
2013-4531	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN N COLQUITT Standly & Hamilton, LLP	K990392, K001945, K002361, ETC
2013-4532	06/11/2013 07/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	AEGERION PHARMACEUTICALS INC - JUXTAPID (LOMITAPIDE) EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2013-4533	06/11/2013 07/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	NPS PHARMACEUTICALS INC - GATTEX (TEDUGLUTIDE) INJ EIRS, 483S, UNTITLED LTRS 1/13 TO PRESENT
2013-4534	06/11/2013 07/10/2013	FDA/OF/CFSAN/OCDE/EOS/	ALISON YOUNG USA TODAY	CRAZE - CAERS
2013-4535	06/11/2013 07/10/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ALISON YOUNG USA TODAY	RIGER; LABORATORIOS RIGER NATURAL SAI, JALISCO, MX - ENTRY 112-4819729-0 IMPORT REFUSAL RPT; RIGER NATURAL - CALZADE DE TIALPAN ENTRY 112-1341824-2 IMPORT REFUSAL RPT; RIGER NATURAL SAI - CARR NACIONAL ENTRY 112-7520250-0 IMPORT REFUSAL RPT
2013-4536	06/11/2013 07/10/2013	FDA/OC/OES/DFOI/	SPILLER JR, ROBERT M	THE DATE OF LAST RPTS SUMMARIZING ALL JUDGMENTS DECREES & COURT ORDERS WHICH HAVE BEEN RENDERED UNDER THIS ACT 21 USC 705 (A); LINK OR LOCATION OF THE LAST PUBLISHED RPT #13; EXPLAIN THE DECISION BY THE SECRETARY TO DISCONTINUE PUBLICATION OF THES STATUTORILY-REQUIRED PRTS 1/1/08 TO 6/7/13
2013-4537	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	RYAN J O'NEIL DUANE MORRIS LLP	STRYKER CORP - CERVICORE INTERVIEWTEBRAL DISC P090011 COMM, PRESENTATIIONS, ANALYSES, ETC 7/04 TO 2/12
2013-4538	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEN PFAEHLER, ESQ DENTONS US LLP	STRYKER CORP - FLEXICORE INTERVERTABRAL DISC P070011 COMM, PRESENTATIONS, ANALYSES, ETC
2013-4539	06/11/2013 07/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	OFF - LABEL LDENTAL IMPLANT DVC - INVESTIGATION RECS
2013-4540	06/11/2013 07/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BEVAN #182723, JOHN D	AMBEIN, AMBIEN CR (ZOLPIDEM TARTRATE); CARBRITAL (PENTOBARBITAT, CARBROMAL); DALMANE (FLUAZEPAM HCL), ETC -AERS LAST 10 YRS
2013-4541	06/11/2013	FDA/OGROP/ORA/SE-FO/ATL-	WILLIAM REYNOLDS	SPINAL SOLUTIONS LLC - EIR 2011

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	07/10/2013	DO/ATL-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	FIRST I INVESTIGASTIONS	
2013-4542	06/11/2013 07/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MOSES LEBOVITS DANIELS FINE ISRAEL ET AL	ATRICURE INC - ATRICURE ATRICLIP LAS EXCLUSION SYS WITH PRELOADED GILLINOV-COSGROVE CLIP APRVL, SUBMISSIONS, MODIFICATIONS, ETC
2013-4543	06/11/2013 07/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEVIN STRANGE WELLS FARGO SECURITIES	ST JUDE MEDICAL - WARNING LTR UPDATES 1/10/13
2013-4544	06/11/2013 07/10/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	JUAN SANEHCZ TULSA CHANNEL 8	SWAN BOTHERS DAIRY, CLAREMORE, OK - RECS
2013-4545	06/11/2013 08/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	SARA A STRICKLAND MORELLI RATNER PC	BAXTER HEALTHCARE CORP, GRIFOLS THERAPEUTICS INC, GRIFOLS USA CORP, ETC - HEPATITIS C VIRUS INTRAVENOUS IMMUNOGLOBULIN (IVIG) REC 2000 TO PRESENT
2013-4546	06/11/2013 07/10/2013	ORA/ ORA/	WJHL-TV	COMPOUNDING PHARMACIES IN TENNESSEE 5/30/11 PRESENT
2013-4547	06/11/2013 07/10/2013	FDA/OC/OES/DDM/	SAMANTHA HERBERT GOODWIN PROCTER LLP	DKT FDA-2013-N-0243
2013-4548	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	R. SCOTT CAMPBELL SHIVER HAMILTON	SYMBIOS MEDICAL PRODUCTS LLC - DISPOSABLE INFUSION PUMP KIT GO PUMP RAPID RECOVERY SYS K072921
2013-4549	06/12/2013 07/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ARTHUR HILSCHER MANNKIND CORP	PULMOZYME DORMASE ALFA BLA 103532 - SBA
2013-4550	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Daan De Coster University College London and Cochrane Collaboration	TRIALS TO SUPPORT UNSUCCESSFUL LICENSING APPLICATIONS FOR BECLOMESTASONE INHALERS IN COPD
2013-4551	06/12/2013 07/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea J Mesaros Fresenius-Kabi USA	Form 483, EIR and responses resulting from the 2011 FDA inspection of Gador, S.A. Pharmaceutical Ingredients Division Calle 10 No. 103 Parque Industrial Pilar Pilar B1630CFA Bs. As., Argentina
2013-4552	06/12/2013 07/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 017443, ANDA 076856 - SBA

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2013-4553	06/12/2013 07/11/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Richard C. Mason, Esq. COZEN O'CONNOR PC	ARENESP, AMGEN, AMERISOURCEBERGEN CORP - INVESTIGATION RECS
2013-4554	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberlee Washburn Kimberlee Washburn	K083009
2013-4555	06/12/2013 07/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 018147 - SBA
2013-4556	06/12/2013 07/11/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	A copy of the firm's responses for inspections performed from January 1, 2011 to March 20, 2013 for: JHP Pharmaceuticals, Rochester, MI
2013-4557	06/12/2013 07/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Florence Bourgeois Boston Children's Hospital Informatics Program	RITALIN, RITALIN SR, CYLERT ETC - STATISTICAL REVIEWS OF INITIAL APPROVAL PACKAGE OR NEXT AVAILABLE REVIEW; BIPHETAMINE - LABEL
2013-4558	06/12/2013 07/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 017473 - SBA
2013-4559	06/12/2013 07/11/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Kevin Engholdt Infinitum Health, LLC	EUROPHARMA CO, INC - RESPONSES TO WARNING LETTER (04/24/2013 - 06/14/2013)
2013-4560	06/12/2013 07/11/2013	FDA/OF/CFSAN/OCDEOS/	BORODIN, DMITY	GLUTINATE (GLUTIOUS) INFO
2013-4561	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K962396
2013-4562	06/12/2013 07/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Timothy Bassett Pura Vida Investments	TACFIDERA, JAKAFI - AERS

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-4563	06/12/2013 07/11/2013	FDA/OMPT/CTP/OD/	Teresa Nazario KYW-TV	ELECTRONIC CIGARETTES - AERS
2013-4564	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alastair Monk Cupron Inc	K061242
2013-4565	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	P040047
2013-4566	06/12/2013 07/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Oren Milgram Novalere FP, Inc.	NONPRESCRIPTION DRUGS ADVISORY COMMITTEE - ANNOUNCEMENT OF MEETING (06/01/2013 - 06/12/2013)
2013-4567	06/12/2013 07/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANNETTE PAUL AURORA BAY CARE MEDICAL CENTER	TRANSCRIPT FECAL MICROBIOTA FOR TRANSPLANTATION MTG 5/2/13
2013-4568	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	PATRICK P. MEVS MARTIN CLEARWATER & BELL	TEMODAR - CLNCL TRIALS
2013-4569	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	W.E. CHALKLEY THOMSON REUTERS	PFIZER PHARMS - ACCURETIC (HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE) NDA 020-125 LBLG
2013-4570	06/12/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	EDWIN H. CLARK CLARK LAW OFFICE	INDIVIDUAL RECS
2013-4571	06/12/2013 07/11/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	SETH M. HYATT BARRETT JOHNSTON LLC	STANDARD CANDY CO INC - INVESTIGATION
2013-4572	06/12/2013 07/11/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CRAIG TRAUTMAN INTAGRAS INC	DRUG LISTINGS NOT POSTED ON NLM

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-4573	06/12/2013 07/11/2013	FDA/OC/OES/DDM/	CATHERINE M. DICKENSON BRYAN CAVE LLP	DKT FDA-2007-P-0190 CERTIFIED COPY
2013-4574	06/12/2013 07/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAY L.T. BREAKSTONE PARKER & WAICHMAN ATTYS	MEDTRONIC - INFUSE BONE GRAFT RHBMP-2; LT CAGE INFUSE BONE GRAFT LUMBAR TAPERED FUSION DVC CORR
2013-4575	06/13/2013 07/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	AUDREY SWEARINGEN EMERGO GROUP INC	ZIMMER - NOBEL REPLACE IMPLANT SYS ZFX ABUTMENT K120873
2013-4576	06/13/2013 07/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAAN DE COSTER UNIV COLLEGE LONDON & COCHRANE COLLABORATION	BECLOMETASONE INHALERS - TRIALS
2013-4577	06/13/2013 07/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OGROP/ORAPA-FO/SAN- DO/SAN-CB/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	KYPROLIS (CARFLIZOMBI INJ) - AERS; ONYX PHARMACEUTICALS INC - EIRS, 483S, UNTITLED LTRS 6/12 TO PRESENT
2013-4578	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	Perez, Patricia L	MINOR DELETIONS
2013-4579	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	Doe J	INDIVIDUAL RECS
2013-4580	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	ELISSA FLYNN-POPPEY MINTZ LEVIN ET AL	ARIAD PHARMACEUTICALS INC - ICLUSIG, PONATINIB RECS 3/1/12 TO 6/11/13
2013-4581	06/13/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROSIERE, SHAUN	LIST OF COMPANIES THAT HAVE APPLIED FOR NDA'S, ANDAS LAST 90 DAYS; NUMBER OF NDA, ANDA APPLICATIONS PER YR 2000 TO PRESENT
2013-4582	06/13/2013 07/12/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA DISCLOSURE LOG (06/03/2013 - 06/07/2013)
2013-4583	06/13/2013 07/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	david petrocine Aceto Corporation	SHENZHEN HEPALINK PHARMACEUTICAL CO, CHINA - EIR, 483 (01/01/2011 - 08/01/2011)

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2013-4584	06/13/2013 07/12/2013	FDA/OF/CFSAN/OCD/EOS/	John O'Loughlin Weil, Gotshal & Manges, LLP	TOPO CHICO MINERAL WATER - COMPLAINTS, FDA ACTIONS (01/01/2013 - 06/11/2013)
2013-4585	06/13/2013 07/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Regena Rosati Cornerstone Research	DRUGS WITH BLACK BOX WARNINGS - NAMES, DATES, INDICATIONS ETC
2013-4586	06/14/2013 07/15/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Scott Talbot Novel Laboratories	OHM LABORATORIES, NEW JERSEY - 483 (12/01/2012 - 12/31/2012)
2013-4587	06/14/2013 07/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Daniel Simpson LIFESOUTH COMMUNITY BLOOD CENTERS INC	BK120067
2013-4588	06/14/2013 07/15/2013	ORA/ ORA/ FDA/OGROP/ORACE-FO/NOL- DO/NOL-CB/ ORA/ ORA/	Monique V. Robinson SEECA Medical, Inc.	TESTING RESULTS
2013-4589	06/14/2013 07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Edward E. Lisberg, MD Asthma and Allergy Center of Chicago, SC	K87379317, K83203719
2013-4590	06/14/2013 07/15/2013	ORA/ ORA/ FDA/OGROP/ORACE-FO/DIOP/	Mark Prinz Registrar Corp	RED LIST, ACTIVE IMPORT ALERT - LIST OF COMPANIES
2013-4591	06/14/2013 07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	IFRAN A. LATEEF KNOBBE MARTENS OLSON & BEAR	COVIDIENS - OXIMAX PULSE OXIMETER MODEL N-600X K123581
2013-4592	06/14/2013 07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	FOI Services, Inc.	REDACTED 510KS 5/13
2013-4593	06/14/2013 07/15/2013	FDA/OGROP/ORACE-FO/LOS- DO/LOS-CB/	MUJIB U. QIDWAI GRIFOLS BIOLOGICALS INC	BAXTER PLASMA, ANGELES, CA - EIR 10/10 TO 10/12
2013-4594	06/14/2013 07/15/2013	FDA/OGROP/ORACE-FO/DIOP/ ORA/ ORA/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	ALL IMPORTS FROM 5/20/13 TO 6/15/13

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2013-4595	06/14/2013 07/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLLEEN M. HEISEY JONES DAY	BETHKIS (TOBRAMYCIN INHALATION SOLUTION) NDA 20-1820 - LBLG RVW, MEDICAL RVW, CHEMISTRY RVW
2013-4596	06/14/2013 07/15/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165504 5/14/13
2013-4597	06/14/2013 07/15/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165500 5/20/13
2013-4598	06/14/2013 07/15/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	JENNIFER SMITH CIVIL & ENVIRONMENTAL CONSULTANTS INC	OXUS ENVIRONMENTAL, PITTSFIELD, ME - INVESTIGATIONS
2013-4599	06/14/2013 07/15/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	JOHNATHAN CARLSON WNCN NEWS	GATE GOURMET #302 - INSP 11/29/12
2013-4600	06/17/2013 07/16/2013	CVM/OCD/	MCKENZIE CATO Hyman, Phelps & McNamara, P.C.	BACKGROUND LEVELS OF DIOXIN AND DIOXIN-LIKE COMPOUNDS IN ANIMAL FEED - FIELD ASSIGNMENTS FOLLOW-UP RECS
2013-4601	06/17/2013 07/16/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	CHRISTINE RAMETTE SURETY CLAIMS INC	AZTECA CANDIES INC - ENTRY #BKM-0028627-8 INVOICES, NOTICES OF ACTION, PACKING LISTS, ETC
2013-4602	06/17/2013 07/16/2013	FDA/OO/OHR/	RICHARD S LUNDIN NICKELSPORN & LUNDIN PC	INDIVIDUAL RECS
2013-4603	06/17/2013 07/16/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JONATHAN B NACE PAULSON & NACE	ABBOTT LABS - HUMIRA POST-APRVL SAFETY STUDIES; TREXALL, RHEUMATREX (METHOTREXATE) AERS 1998 TO 2012, ETC
2013-4604	06/17/2013 07/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	TOSHIO MURATA NIDEK INC	OCULUS OPTIKGERATE GMBH - PENTACAM SHEIMPFLUG CAMERA K030719
2013-4605	06/17/2013 07/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SARAH BUDUSON WEWS - NewsChannel5	PRADAXA - AERS 10/10 TO 6/15/13

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-4606	06/17/2013 07/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DEBRA HATHAWAY THINC PHARMA	AMITIZA (LUBIPROSTONE) NDA 21-908/S010,S011 - RVWS, CORR
2013-4607	06/17/2013 07/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	LORI PFOHL TELEFLEX MEDICAL	KIMBERLY-CLARK - KIMVENT MICROCUFF SUBGLOTTIC SUCTIONING TUBE K120985
2013-4608	06/17/2013 07/16/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 06/10/2013 - 06/14/2013
2013-4609	06/17/2013 07/16/2013	FDA/OMPT/CTP/OD/	Mark Zdechlik MINNESOTA PUBLIC RADIO NEWS	ELECTRONIC CIGARETTES - AERS DATABASE
2013-4610	06/17/2013 07/16/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	CONSUMER COMPLAINT
2013-4611	06/17/2013 07/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jocelyn Polito X-GEN PHARMACEUTICALS INC	CHONGQING PHARMA RESEARCH INSTITUTE CO, LTD, CHONGGQING, CHINA - EIR,483 (07/26/2010 - 07/30/2010)
2013-4612	06/17/2013 07/16/2013	FDA/OC/OES/DDM/	John Chan UNIVERSITY OF CALIFORNIA, SAN FRANCISCO	ONCOLOGY DRUG ADVISORY COMMITTEE MEETING MINUTES, TRANSCRIPTS (01/01/1982 - 01/01/1998)
2013-4613	06/17/2013 07/16/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	John Walsh James Alexander Corporation	P&G CHEMICALS, CINCINNATI, OH - EIR, 483 (06/14/2010 - 06/14/2013)
2013-4614	06/17/2013 07/16/2013	FDA/OC/OES/DFOI/	COOPER 328257, JACK	SUBOXONE, ROXY, PERCOCET - RECS
2013-4615	06/17/2013 07/16/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	DUFFY, TAMMY	CMPLNT 131636
2013-4616	06/17/2013 07/16/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	Yingchao Xiao Lee & Xiao	AF4-0581272-4/2/1

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2013-4617	06/17/2013 07/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sinem Tan MN Pharmaceuticals-Mustafa Nevzat Ilac	MUSTAFA NEVZAT ILAC SANAYII A.S., INSTANBUL - EIR 04/20/12 - 05/03/12
2013-4618	06/17/2013 07/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	RODNEY VAN DE HOEF VANDEHOEF, Rodney A	PRO LASER III, LIDAR - OUTPUT, MILLITATT RATING, ADVERSE EVENTS
2013-4619	06/17/2013 07/16/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Curtis Walcker VRP Manufacturing, LLC	HILLESTAD PHARMACEUTICALS US, INC - 483, CORR (07/01/2012 - 06/11/2013)
2013-4620	06/17/2013 07/16/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	DAGES, Joe. THOMPSON, Jackie. Keller and Heckman LLP	WARNING LETTER RESPONSES, ENFORCEMENT ACTION RECS
2013-4621	06/17/2013 07/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eriko Yagi E. Yagi	SKYE PHARMA - 483, WARNING LETTER (10/01/2001 - 10/01/2006)
2013-4622	06/17/2013 07/16/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eriko Yagi E. Yagi	ALZA - 483, WARNING LETTER (05/01/1993 - 11/01/2001)
2013-4623	06/17/2013 07/16/2013	FDA/OC/OES/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058, FDA-2013-P-0119, ETC.
2013-4624	06/18/2013 07/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	PCAS FINLAND OY, TURKU, FINLAND - EIRS, 483S, CO RESP 2/08/13
2013-4625	06/18/2013	FDA/OGROP/ORA/CE-FO/DET-	WALTER E CHALKLEY	BAXTER PHARMACEUTICALS SOLUTIONS LLC,

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	07/17/2013	DO/DET-CB/	THOMSON REUTERS	BLOOMINGTON, IN - EIRS, 483S, CO RESP 03/12/13
2013-4626	06/18/2013 07/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMBI PHARMACEUTICALS INC, BROOKSVILLE, FL - EIRS, 483S, CO RESP 03/30/12
2013-4627	06/18/2013 07/17/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMAG PHARMACEUTICALS INC, LEXINGTON, MA - EIRS, 483S, CO RESP 02/07/13
2013-4628	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	ACTAVIS ELIZABETH LLC, ELIZABETH, NJ - EIRS, 483S, CO RESP 02/15/13
2013-4629	06/18/2013 07/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	WHITNEY LABS LP, ORMOND BEACH, FL - EIRS, 483S, CO RESP 01/26/12
2013-4630	06/18/2013 07/17/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	TITAN MEDICAL ENTERPRISES INC (DBA US APOTHECARY LABS), SANTA FE SPRINGS, CA - EIRS, 483S, CO RESP 01/15/13
2013-4631	06/18/2013 07/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	TG UNITED PHARMACEUTICALS INC, BROOKSVILLE, FL - EIRS, 483S, CO RESP 03/30/12
2013-4632	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMERICAN NATIONAL RED CROSS, COLUMBUS, OH - EIRS. 483S, CO RESP 03/15/13
2013-4633	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS PHARMA BPO, HUNINGUE, FRANCE - EIRS, 483S, CO RESP 01/31/12
2013-4634	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDIMMUNE LLC, GAITHERSBURG, MD - EIRS, 483S, CO RESP 03/20/13
2013-4635	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	MCKESSON MEDICAL SURGICAL, SWEDESSBORO, NJ - EIRS, 483S, CO RESP 12/08/11
2013-4636	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELI LILLY & CO, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 02/14/13
2013-4637	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	KREMSERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN - EIRS, 483S, CO RESP 10/31/12
2013-4638	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WASLTER E CHALKLEY THOMSON REUTERS	INOVA HEALTH CARE SERVICES, INOVA BLOOD DONOR SERVICES, STERLING, VA - EIRS, 483S, CO RESP 02/13/12
2013-4639	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELBA INC (ELBA LABORATORIES), TROY, MI - EIRS, 483S, CO RESP 09/27/12

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2013-4640	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	DPT LAKEWOOD LLC, LAKEWOOD, NJ - EIRS, 483S, CO RESP 09/27/12
2013-4641	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CSL PLASMA INC, BELOIT, WI - EIRS, 483S, CO RESP 02/20/13
2013-4642	06/18/2013 08/26/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	COREPHARMA LLC, MIDDLESEX, NJ - EIRS, 483S, CO RESP 06/11/12
2013-4643	06/18/2013 07/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARDINAL HEALTH 414 LLC, TAMPA, FL - EIRS, 483S, CO RESP 03/19/13
2013-4644	06/18/2013 07/17/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	BROWN MD, RAYMOND, PHILADELPHIA, PA - EIRS, 483S, CO RESP 01/29/13
2013-4645	06/18/2013 07/17/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BOEHRINGER INGELHEIM PHARMACEUTICALS INC, DANBURY, CT - EIRS, 483S, CO RESP 01/30/13
2013-4646	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	WOCKHARDT LIMITED, AURANGABAD, INDIA - EIR (03/01/2013 - 06/13/2013)
2013-4647	06/18/2013 07/17/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Adam Bobkin MILBERG LLP	MARC HERMELIN, K-V PHARM, ETHEX CORP - VARIOUS RECS
2013-4648	06/18/2013 07/17/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	2012-4834, 2012-8511, 2013-2393
2013-4649	06/18/2013 07/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Naoto Fujikawa Takeda Pharmaceutical Company Limited	NEW MOLECULAR ENTITIES APPROVED AS DRUGS BETWEEN 1/1/1985 AND 12/31/2012
2013-4650	06/18/2013 07/17/2013	CVM/OCD/	Judith Hill INTERTEK CANTOX	AMMONIUM FORMATE - FOOD ADDITIVE PETITIONS
2013-4651	06/18/2013 07/17/2013	ORA/ORM/ ORA/ORM/	b. burgess BURGESS, BERNIE	LIST OF INSPECTIONS CONDUCTED BY LOS-DO FY 2007
2013-4652	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	D. Jonathan Corbin D Jonathan Corbin	IND RECS FOR ANY DRUG CONTAINING 3-BROMOPYRUVATE OR CHEMICAL ANALOGS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4653	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr J-I. Schafer Electro Medical Geratebau GmbH	K862106
2013-4654	06/18/2013 07/17/2013	FDA/OMPT/OSMP/OOPD/	Stanley Satz Advanced Imaging Projects, Inc.	FERUMOXYTOL - OOPD DESIGNATION RECS
2013-4655	06/18/2013 07/17/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	FACTS 808885 - ORA FINANCIAL DOCUMENTS
2013-4656	06/18/2013 07/17/2013	CVM/OCD/	Judith Hill Internek Cantox	POLYSORBATE 80 - FOOD ADDITIVE PETITIONS
2013-4657	06/18/2013 07/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Bradley UNIVERSITY OF CALIFORNIA SAN DIEGO	NDA 050720, 050725, 050726
2013-4658	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden Corporation	K123581
2013-4659	06/18/2013 07/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ashley Yeager The Simon Law Firm	INTRAVENOUS ADMINISTRATION OF BYNTYL - AERS
2013-4660	06/18/2013 07/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	WOCKHARDT LIMITED, INDIA - 483 (03/01/2013 - 06/14/2013)
2013-4661	06/18/2013 07/17/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	JoNel Aleccia MSNBC.COM	TOWNSEND FARMS, FAIRVIEW, OR - EIR, 483, WARNING LETTER (05/01/2013 - 06/14/2013)
2013-4662	06/18/2013 07/17/2013	FDA/OMPT/CTP/OD/	Doe J	INDIVIDUAL RECS
2013-4663	06/18/2013 07/31/2013	ORA/ ORA/	Mark Prinz Registrar Corp	FDA PRIOR NOTICE INFORMATION SUBMITTED TO FDA (01/01/2013 - 01/31/2013)
2013-4664	06/18/2013 07/17/2013	FDA/OMPT/CTP/OD/	Chris Murphy Valor Equity Partners	PLOOM MODEL ONE - FDA CLASSIFICATION RECS
2013-4665	06/18/2013 07/17/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Jody Roberts Mind Research Network	UNIVERSITY OF NEW MEXICO HEALTH SCIENCES CENTER - 483 (01/01/2013 - 06/17/2013)

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2013-4666	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now Saint Gobain PPL)	K933228
2013-4667	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now Saint Gobain PPL)	K870865
2013-4668	06/18/2013 07/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Leanne Usa WOCKHARDT USA INC	ANDA 88-312
2013-4669	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now part of Saint Gobain)	MAF 1143
2013-4670	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Wendy Linthicum American Fluoroseal Corporation (now part of Saint Gobain)	MAF 1506
2013-4671	06/18/2013 07/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rebecca Walters AtriCure, Inc.	K090202, K120857
2013-4672	06/18/2013 07/17/2013	CVM/OCD/	Sarah Dumas UNIVERSITY OF ILLINOIS	NADA 055-030 FOIA SUMMARY
2013-4673	06/19/2013 07/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 091619 - SBA
2013-4674	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring Quality & Regulatory Associates, LLC	K970951
2013-4675	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Gary Syring Quality & Regulatory Associates, LLC	K884937
2013-4676	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary Syring SYRING, GARY J	K033978
2013-4677	06/19/2013 07/18/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Constance M Williams Williams, Constance M	LUPRON - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4678	06/19/2013 07/18/2013	CVM/OCD/	John Russell The Indianapolis Star	ANIMAL DRUG APPROVALS 01/01/1993 - 12/31/2008
2013-4679	06/19/2013 07/18/2013	FDA/OMPT/OSMP/OOPD/	Timothy Cote Cote Orphan Consulting	EPOETIN ALFA - ORPHAN PRODUCT DESIGNATION RECS
2013-4680	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Strickler CBS EVENING NEWS	NEXIUM, ABILIFY, CRESTOR ETC - DRUG MASTER FILE
2013-4681	06/19/2013 07/18/2013	FDA/OC/OES/DDM/	SAMANTHA HERBERT GOODWIN PROCTER LLP	DKT FDA-2009-M-0101
2013-4682	06/19/2013 07/18/2013	FDA/OC/OES/DDM/	ROSS RENDELMAN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058, FDA-2013-P-0119, ETC.
2013-4683	06/19/2013 07/18/2013	OC/OCC/	DANA A. PRIVU EPSTEIN BECKER & GREEN PC	HOME BREW LAB TESTS
2013-4684	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAREN COLLINS HARDISON COCHRAN	MIRENA IUD - LGLG 2000 TO 2013
2013-4685	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN C. SCHULTE WINSTON & STRAWN LLP	BRAIN LAB AG - NOVALIS SHAPED BEAM SURGERY SYS 510K
2013-4686	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	IAN McALLISTER KREINDLER & KREINDLER	SMITH & NEPHEW - R3 CONSTRAINED LINER K111635 6/9/11
2013-4687	06/19/2013 07/18/2013	FDA/OO/OFBA/OAGS/	KREINDLER & KREINDLER	BILDERBERG CONFERENCE - CORR 2008 TO 2013
2013-4688	06/19/2013 07/18/2013	FDA/OC/OES/DFOI/	CORBIN, D JONATHAN .	1305533; 1305537
2013-4689	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAREN MARTINI YES PHARMACEUTICAL	PFIZER - ADVIL CONGESTION RELIEF SAFETY RTP
2013-4690	06/19/2013 07/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	McGEE B10590, CLAUDE	ANTERIOR LUMBAR DISK & FUSION - APRVL

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2013-4691	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHELLEY WHITE FIGARI & DAVENPORT	AVASTIN (BEVACIZUMAB) - EFFICACY
2013-4692	06/19/2013 07/18/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	STEPHEN C. SCHULTE WINSTON & STRAWN LLP	VARIAN MEDICAL SYS - 4D INTEGRATED TREATMENT CONSOLE - RECALL 10/16/09
2013-4693	06/19/2013 07/18/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	MINDY GOLDSTEIN, Esq. EMORY SCHOOL OF LAW	FDA FOOD PROCESSING SECTOR STUDY FINAL RPT 11/11
2013-4694	06/19/2013 07/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	INTERMUNE PHARMS - ACTIMMUNE (INTERFERON GAMMA-1B) BLA 10-3836 APRVL, LBLG
2013-4695	06/20/2013 07/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LAYNE STACKHOUSE JONES WARD PLC	MIRENA (LEVONORGESTREL-RELEASING) INTRAUTERINE DVC - CLNCL TRIALS, RPTS, CORR, ETC
2013-4696	06/20/2013 07/19/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDANEWS	LIST OF 483S FOR PHARMACEUTICAL, BIOLOGICS & MEDICAL DVC MFG BOTH IN THE US & OUTSIDE THE US 5/1-31/13
2013-4697	06/20/2013 07/19/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	HUVEPHARMA INC, ST LOUIS, MO - EIRS, 483S 1/2/13 TO PRESENT
2013-4698	06/20/2013 07/19/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	BRENDA M GARTZ ELI LILLY & CO	MANNKIND CORP, DUANBURY, CT - EIRS 2009 TO PRESENT
2013-4699	06/20/2013 07/19/2013	FDA/OC/OES/ OC/OL/ FDA/OC/OPP/OP/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/OIP/ ORA/ ORA/	ABRAHAM PAYTON AMERICAN BRIDGE 21ST CENTURY	REP DAVID JOYCE & FDA COMMISSIONER, DEPUTY COMMISSIONER, ASSOCAITE COMISSIONER, ETC 1/3/13 TO PRESENT; FRANCIS J FRANK SASINOWSKI & FDA COMMISSIONER, DEPUTY COMMISSIONER, ASSOCIATE COMISSIONER, CORR ETC

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2013-4700	06/20/2013 07/19/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SHELLY REILLY AARP	CRYSTAL CARE INTERNATIONAL INC, LUTZ, FL - WARNING LTR 5/22/09 COMPLIANCE WITH REGULATIONS
2013-4701	06/20/2013 07/19/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ ORA/ ORA/	BRAD HODGES FREMONT FARMS LLC	FREMONT FRAMS LLC -SPL 800442 - ANALYTICAL RPT 5/31/13
2013-4702	06/20/2013 07/19/2013	FDA/OF/CFSAN/OCD/EOS/	JASON A DEAN Hulsey Oliver & Mahar, LLP	JARCHEM INDUSTRIES INC - FOOD FACILITY REGISTRATION NO 10526878760
2013-4703	06/21/2013 07/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Sonali Gunawardhana Wiley ReinLLP	KERRY INGREDIENTS AND FLAVORINGS - EIR, 483, CORR (02/01/2013 - 06/14/2013)
2013-4704	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Bohn Bohn, Elizabeth	VIVIAN - APPROVAL RECS
2013-4705	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121474
2013-4706	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100723
2013-4707	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103470
2013-4708	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120179
2013-4709	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100386
2013-4710	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Minnich B. Braun Medical Inc.	K110901
2013-4711	06/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kellin Chatfield	K925008

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	07/22/2013		DLA Piper LLP (US)	
2013-4712	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED AND RELEASED IN MAY 2013
2013-4713	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2539
2013-4714	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Allison Scott Esaote, S.p.A.	K070903 K083882 K101605 ETC
2013-4715	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3716
2013-4716	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-3522
2013-4717	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Justin M McFadden STOEL RIVES LLP	DMF 21221
2013-4718	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lisa Suchar self-employed	ADASUVE - SBA
2013-4719	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Theresa Deisher Sound Choice Pharmaceutical Institute	MMRII - APPROVAL LETTERS
2013-4720	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Merlaine Bissainthe Merlaine Bissainthe, Attorney at Law	AMBIEN - AERS
2013-4721	06/21/2013 07/22/2013	FDA/OGROP/ORAP/FO/LOS-DO/LOS-CB/	b. burgess BURGESS, BERNIE	110674 - EIR, ENDORSEMENT

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2013-4722	06/21/2013 07/22/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Tammy Nash OptumRx	OPTUM RX, OVERLAND PARK, KS - EIR (04/02/2012 - 06/18/2013)
2013-4723	06/21/2013 07/22/2013	FDA/OMPT/OSMP/OOPD/	Anne Madej Genentech, Inc.	EXEMESTANE - ORPHAN PRODUCT DESIGNATION
2013-4724	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Thostesen JANSSEN ORTHO LLC	CENEXI - EIR (07/01/2012 - 06/19/2013)
2013-4725	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Majid Iqbal Motherisk	BUPROPION, ESCITALOPRAM - AERS
2013-4726	06/21/2013 07/22/2013	CVM/OCD/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	RACTOPAMINE HYDROCHLORIDE TYPE B LIQUID FEED ANALYTICAL METHOD
2013-4727	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	XELLIA PHARMACEUTICALS, COPENHAGEN, DENMARK - 483, EIR SUMMARIES
2013-4728	06/21/2013 07/22/2013	FDA/OGROP/ORASW-FO/NYK-DO/NYK-DCB/	Paul Knoepfler UC DAVIS	INTELLICELL BIOSCIENCES INC - 483 (03/01/2013 - 06/19/2013)
2013-4729	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	XELLIA PHARMACEUTICALS, COPENHAGEN, DENMARK - EIR
2013-4730	06/21/2013 07/22/2013	FDA/OGROP/ORASW-FO/DET-DO/DET-CB/	Michael E Rettig, R.N. B.S.N. Michael E Rettig, R.N. B.S.N. Legal Nurse Consultant	AXIOBIONICS, LLC, ANN ARBOR, MI - RECALL, WARNING LETTER RECS (01/01/2011 - 06/20/2013)
2013-4731	06/21/2013 07/22/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	Jacki Thompson Keller and Heckman LLP	FDA-2009-D-0430
2013-4732	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	LISINOPRIL - TESTING RECS

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2013-4733	06/21/2013 07/22/2013	CVM/OCD/	Mike Smith Truth in Food/Custom Publications LLC	MILK SAMPLING FIELD ASSIGNMENT RESULTS (11/01/2011 - 06/20/2013)
2013-4734	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals, Inc.	NDA 019779 SBA
2013-4735	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Phylis C Dryden DRYDEN, FORREST	AFINITOR - AERS SUMMARY
2013-4736	06/21/2013 08/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK100056
2013-4737	06/21/2013 07/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 21610 ABUK IMPURITIES
2013-4738	06/21/2013 07/22/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/OIP/	REBECCA CASE LERNERS LLP	STRYKER - REJUVENATE MODULAR-NECK STEMS PRE-MARKET APRVL, MONOGRAPHS, PROD INSERTS, ETC
2013-4739	06/21/2013 07/22/2013	CVM/OCD/	STEPHEN J TELKEN SCHOEN WALTON TELKEN & FOSTER LLC	INDIVIDUAL RECS
2013-4740	06/21/2013 07/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	J KENNETH KRUVANT J KENNETH KRUVANT LAW OFCS	ADVANCED ORTHOPEDIC SOLUTIONS - ES TROCHANTERIC NAIL CMLPTS LAST TEN YRS; INDIVIDUAL RECS
2013-4741	06/21/2013 07/22/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	FRAN SILVERMAN TRUTH IN ADVERTISING.ORG	VERMA NUTRITION CO, SCOTTSDALE, AZ - EIR, 483, CO RESP 11/12
2013-4742	06/21/2013 07/22/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	EVAN BASLER LIFE SOUTH COMMUNITY BLOOD CENTERS	PUGET SOUND BLOOD CENTER, SEATTLE, WA - EIR, 483 1/14/13-2/15/13

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2013-4743	06/24/2013 07/23/2013	FDA/OO/OFBA/OAGS/	Prakash Behrani Platinum Systems, Inc.	HHSF223200950034P - MOST RECENT PROPOSAL
2013-4744	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeffrey Meyerson The Meyerson Law Firm, PLC	K090949
2013-4745	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Davey Leu Mello Biotech	IND 69896
2013-4746	06/24/2013 07/23/2013	FDA/OF/CFSAN/OCD/EOS/	Kristi Wolff Wolff, Kristi	SPHAERANTHUS INDICUS - NEW DIETARY INGREDIENT RECS
2013-4747	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Quan Zhao, Md Phoenix Childrens Hospital	RITUXIMAD - AERS
2013-4748	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tamilselvi.S Quest Lifesciences Pvt Ltd	QUEST LIFESCIENCES PVT LTD, CHENNAI, INDIA - EIR 12/26/2011 TO 12/30/2011
2013-4749	06/24/2013 07/23/2013	FDA/OF/CFSAN/OCD/EOS/	Joshua Valero Capstone Law, APC	KNUDSEN - NUTRIENT CONTENT CLAIMS (CERTIFIED) (06/20/2004 - 06/20/2013)
2013-4750	06/24/2013 07/23/2013	FDA/OF/CFSAN/OCD/EOS/	Joshua Valero Capstone Law, APC	SMUCKER - NUTRIENT CONTENT CLAIMS (CERTIFIED) (6/20/2009 - 06/20/2013)
2013-4751	06/24/2013 07/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott A. Hodes Scott A. Hodes, Attorney at Law	ICLUSIG - ISR
2013-4752	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3787 - REQUEST LETTER
2013-4753	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3744 - REQUEST LETTER
2013-4754	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3639 - REQUEST LETTER
2013-4755	06/24/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-3633 - REQUEST LETTER

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	07/23/2013		MERCK & CO., INC.	
2013-4756	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3868 - REQUEST LETTER
2013-4757	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3525 - REQUEST LETTER
2013-4758	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3458 - REQUEST LETTER
2013-4759	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3459 & 2013-3460 - REQUEST LETTER
2013-4760	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3615 - REQUEST LETTER
2013-4761	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3462 - REQUEST LETTER
2013-4762	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3630 - REQUEST LETTER
2013-4763	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3996 - REQUEST LETTER
2013-4764	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3723 - REQUEST LETTER
2013-4765	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4099 - REQUEST LETTER
2013-4766	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3461 - REQUEST LETTER ONLY
2013-4767	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3889 - REQUEST LETTER ONLY
2013-4768	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4020 - REQUEST LETTER ONLY
2013-4769	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3678 - REQUEST LETTER
2013-4770	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3499 - REQUEST LETTER
2013-4771	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3602 - REQUEST LETTER

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2013-4772	06/24/2013 07/24/2013	FDA/OO/OHR/ FDA/OC/OES/	Stacylyn Dewey ROPES & GRAY LLP	INDIVIDUAL RECS
2013-4773	06/24/2013 07/23/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/	Lynn Keefe Lynn Keefe	BRACCO DIAGNOSTICS - 483 (01/01/2008 - 06/19/2013)
2013-4774	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Vivianne Noetzel Vivianne Noetzel	K102947, K120711, K130361
2013-4775	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Saleem Musallam Excite Medical corp.	K103248
2013-4776	06/24/2013 07/23/2013	FDA/OC/OES/DDM/	LAUREN FAMEGGIA Hyman, Phelps and McNamara	OTC VOL 210421, 210014, ETC.
2013-4777	06/24/2013 07/23/2013	FDA/OC/OES/DDM/	LAUREN FAMEGGIA Hyman, Phelps and McNamara	OTC VOL 210013
2013-4778	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - OSTEORAPTOR K082215
2013-4779	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	ARTHREX - INTERFERENCE SCREW K062466
2013-4780	06/24/2013 07/23/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - BIORAPTOR 2.3 PK SUTURE ANCHOR 071586
2013-4781	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	PROMEDICAL PRODUCTS CO LTD, LIYANG, CHINA - EIR, 483
2013-4782	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	PARCUS - KNOTLESS PEEK CF PUSH IN SUTURE ANCHORS K113730
2013-4783	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - BIOSURE PK INTERFERENCE SCREW K083635
2013-4784	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	R.O. DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	SMITH & NEPHEW - TWINFIX ULTRA HA SUTURE ANCHOR K093844
2013-4785	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	JANET COOPER WESTMED INC.	CIRCUIT BREATHING W CONNECTOR ADAPTER Y PIECE K904538

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2013-4786	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER WESTMED INC.	AMERICAN MEDICAL SYS INC - SUGICAL MESH DVC FOR PELVIC FLOOR REPAIR K023516
2013-4787	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 77-575
2013-4788	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 91-226
2013-4789	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 77-830
2013-4790	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 78-773
2013-4791	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	A. LUKE SMITH, Esq. FARUQI & FARUQI LLP	ANDA 90-548
2013-4792	06/24/2013 07/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BETH ZIEMBA CELL THERAPEUTICS INC	TOSEDOSTAT - FAERS
2013-4793	06/24/2013 07/23/2013	FDA/OF/CFSAN/OCD/EOS/	GEORGE G. MISKO Keller and Heckman LLP	4/9/2013 CONFERENCE IN NEW ORLEANS, LA - AUDIO OF POWERPOINT PRESENTATION "RISK ASSESSMENT OF CYCLIC SILOXANES OCTAMETHYLCYCLOTETRAILOXANE"
2013-4794	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC K011251 - REVIEWER NOTES, MTG MINS
2013-4795	06/24/2013 07/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	CHRISTINE S. RICHARD INDAGO GROUP	INTUITIVE - SURGICAL DA VINCI ROBOT MAUDE DATA
2013-4796	06/25/2013	FDA/OMPT/CDER/ORP/DIDP/	Nancy Kotlowski	HUMIRA - AERS

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	07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Baxter Baker Sldle Conn & Jones, LLP	
2013-4797	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	soma das The Economic Times, Times of India	RANBAXY - 483 (04/04/2012 - 06/12/2013)
2013-4798	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Strickler CBS NEWS	RANBAXY 483 (01/01/2013 - 06/24/2013)
2013-4799	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barbara J. Lipshutz Jacobs & Burleigh LLP	CORAD HEALTHCARE, INC - REGISTRATION STATUS, DRUGS MANUFACTURED OR DISTRIBUTED, 483 ETC
2013-4800	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ayesha Adil The Weinberg Group	ANDA 78912
2013-4801	06/25/2013 07/24/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Brad Averill Green Valley Group, LLC, dba Wildtime Foods	WILDTIME FOODS, EUGENE, OR - EIR MARCH 2013
2013-4802	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	MAQUET - COMPLIANCE CORR, INVESTIGATION
2013-4803	06/25/2013	FDA/OMPT/CDER/GRP/DIDP/	soma das	RANBAXY, MOHALI, INDIA - 483 (02/01/2012 - 06/06/2013)

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	07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	The Economic Times,Times of India	
2013-4804	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/	Francis Thevenet AIDGUM/AIPG	TRAGACANTH GUM PUBLICATIONS
2013-4805	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tim Henkel VenatoRx Pharmaceuticals, Inc.	NDA 050706
2013-4806	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Muna Shikaki Al Arabiya	RANBAXY - 483 (01/01/2013 - 06/24/2013)
2013-4807	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Natasha Singer THE NEW YORK TIMES	GNC, ANDERSON, SC, LEETSDALE, PA (05/01/2013 - 06/24/2013) - INSPECTION RECS, REQUEST TO DETAIL DMAA CONTAINING PRODUCTS
2013-4808	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Josh Scheinblum KGAN	RANBAXY - 483 (01/01/2013 - 06/24/2013)
2013-4809	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Kolodny MD Physicians for Responsible Opioid Prescribing	EMAILS TO OR FROM DOUGLAS THROCKMORTON RE HYDROCODONE
2013-4810	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gary McGarity Gary J McGarity, PharmD	ACULAR OPHTHALMIC SOLUTION OR KETOROLAC ORAL OR INJECTABLE - NEUROTOXICITY

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2013-4811	06/25/2013 07/24/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT DETERMINATION FOR GF1200548
2013-4812	06/25/2013 07/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dr. Remington L. Nevin Johns Hopkins Bloomberg School of Public Health	AERS 8504150
2013-4813	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/	Kyle Herink Kemin Industries, Inc.	AMMONIUM FORMATE - FAP
2013-4814	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/	Jessica Swanson Innovative Science Solutions	SUCRALOSE - AERS
2013-4815	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Lara N. Simmons Northpoint Services - Medline Industries, Inc.	NORTHPOINT SERVICES, WAUKEGAN, IL - EIR 10/01/2011 - 11/01/2011
2013-4816	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Manfred Steiner Ratio Health USA inc	FDA CORR WITH HAROLD M HOFFMAN
2013-4817	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/	Thenell & Associates LLC 20130620 THENELL & ASSOCIATES LLC	BIOTECHNOLOGY NOTIFICATION FILE 000125
2013-4818	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/13-17/13
2013-4819	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/20-24/13
2013-4820	06/25/2013 07/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	BEAFEATERS - CMLPNTS
2013-4821	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 5/27-31/13
2013-4822	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	CLOSED FOIA REQUESTS 6/03-07/13
2013-4823	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESRS 5/13-17/13
2013-4824	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 5/20-24/13

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2013-4825	06/25/2013 07/24/2013	FDA/OF/CFSAN/OCD/EOS/	KATHYRN L CONIGLIO Keller and Heckman LLP	MISSISSIPPI RIVER CORP - RECYCLED PULP LTR OF NO OBJECTION CORR, SAFETY ASSESSMENTS, TOXICOLOGY RVWS, ETC
2013-4826	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE - AERS
2013-4827	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	FOI DAILY LOG 5/27-31/13
2013-4828	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARY B SZALKOWSKI PRISMA CORP	INDAPAMIDE - ISRS 9112795, 9135479, 9157753; PERINDOPRIL - ISRS 893672, 9028946, 9055527
2013-4829	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DAVID MCFARLAND FDA REVIEW/FDA WEBVIEW	CLOSED FOIA REQUESTS 6/3-7/13
2013-4830	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	CORLEY #58854-006, JOHNNIE	LEGISLATIVE HISTORY ON FEDERAL STATUTE 18 USC 2118 ROBBERY OR BURGLARY OF CONTROLLED SUBSTANCES 1984
2013-4831	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/13-17/13
2013-4832	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	CLOSED FOIA REQUESTS 5/20-24/13
2013-4833	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOIA REQUESTS 5/27-31/13
2013-4834	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOIA REQUESTS 6/3-7/13
2013-4835	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOIA REQUESTS 5/13-17/13
2013-4836	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSEDFOIA REQUESTS 5/20-24/13
2013-4837	06/25/2013 07/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COOK, DELLANA	AC CUTANE - AERS

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2013-4838	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSEDL FOIA REQUETS 5/27-31/13
2013-4839	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	CLOSED FOIA REQUESTS 6/3/7/13
2013-4840	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/13-17/13
2013-4841	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/20-24/13
2013-4842	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 5/27-31/13
2013-4843	06/25/2013 07/24/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	CLOSED FOIA REQUESTS 6/3-7/13
2013-4844	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	BRISTOL-MYERS SQUIBB CO INC - EIRS, 483S, CO RESP 02/07/13
2013-4845	06/25/2013 07/24/2013	OC/OCC/	JENNIFER HSIEH DEERFIELD INSTITUTE	THE MEDICINES CO, FOLEY HOAG - ORITAVANCIN MTG MINS, AGENDA, INTINERARY, ETC 6/13/13
2013-4846	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	3M COMPANY IRB, ST PAUL, MN - EIRS, 483S, CO RESP 10/10/12
2013-4847	06/25/2013 07/24/2013	CVM/OCD/	SILVIA ULM BURDOCK GROUP	PROTEINASE, ENDOPEPTIDASE, PROTEOLYTIC ENZYME - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4848	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/CHI- DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLOSOURCE, CHICAGO, IL - EIRS, 483S, CO RESP 03/12/12
2013-4849	06/25/2013 07/24/2013	CVM/OCD/	SILVIA ULM BURDOCK GROUP	AMYLOGLUCOSIDASE, GLUZYME, DIAZYME, DISTILLASE, OPTIDEX - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4850	06/25/2013 07/24/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BELCHER PHARMACEUTICALS, LARGO, FL - EIRS, 483S, CO RESP 01/07/13

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2013-4851	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOMAT USA INC, DANVILLE, VA - EIRS, 483S, CO RESP 05/12/12
2013-4852	06/25/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXOSMITHKLINE, RIXENSART, BELGIUM - EIRS, 483S, CO RESP 10/05/12
2013-4853	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELORAC INC, VERNON HILLS, IL - EIRS, 483S, CO RESP 01/30/12
2013-4854	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WATER E CHALKLEY THOMSON REUTERS	BOEHRINGER INGELHEIM CHEMICALS INC, PETERSBURG, VA - EIRS, 483S, CO RESP 04/04/12
2013-4855	06/25/2013 07/24/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	GRIFOLS BIOMAT USA INC, POCATELLO, ID - EIRS, 483S, CO RESP 04/24/12
2013-4856	06/25/2013 08/01/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAZZ PHARMACEUTICALS INC, PALO ALTO, CA - EIRS, 483S, CO RESP 05/30/12
2013-4857	06/25/2013 07/24/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	MCR AMERICAN PHARMACEUTICALS INC, BROOKSVILLE, FL - 03/30/12
2013-4858	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	NIEL T CONSTANTINE - EIRS, 483S, CO RESP 08/20/12
2013-4859	06/25/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	SHABLEAU, RAMONA.	DR PAUL J SARATA, CHICAGO, IL - AERS 9/2/11
2013-4860	06/25/2013 07/24/2013	CVM/OCD/	SILVIA ULM BURDOCK GROUP	AMYLASE FROM ASPERGILLUS ORYZAE - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4861	06/25/2013 07/24/2013	CVM/OCD/	SILVIA KIM BURDOCK GROUP	CELLULASE FROM TRICHODERMA REESEI - REGULATORY STATUS, CONSUMPTION, USES AND SAFETY RECS
2013-4862	06/25/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER IRELAND PHARMS, DUBLIN 22, IRELAND - EIR, 483, CO RESP 6/28/12
2013-4863	06/25/2013 07/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	QUADRANT CHEMICAL CORP, GARLAND, TX - EIR, 483, CO RESP 1/4/12

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2013-4864	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	RARITAN PHARMACEUTICALS INC, EAST BRUNSWICK, NJ - EIR, 483, CO RESP 8/21/12
2013-4865	06/25/2013 07/24/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HEALTHCARE MEDICAL & RESPIRATORY CARE INC, HOT SPRINGS, AR - EIR, 483, CO RESP 6/20/12
2013-4866	06/25/2013 07/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SUN PHARMACEUTICAL INDUSTRIES LTD, HALOL, INDIA - EIR, 483, CO RESP 6/13/12
2013-4867	06/25/2013 07/24/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	TG UNITED LABS LLC, BROOKSVILLE, FL - EIR, 483, CO RESP 3/30/12
2013-4868	06/25/2013 07/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TOMASZ ZIELINSKI MD, KATOWICE, POLAND - EIR, 483, CO RESP 8/3/12
2013-4869	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	DR LEONARD VALENTINO, CHICAGO, IL - EIR, 483, CO RESP 8/16/12
2013-4870	06/25/2013 07/24/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	VALIDUS PHARMACEUTICALS INC, PARSIPPANY, NJ - EIR, 483, CO RESP 7/10/12
2013-4871	06/25/2013 07/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ ORA/OCI/ ORA/OCI/	Doe J	LTR OF 9/27/07 FROM DSI, RESP OF 11/29/07; EMAIL OF 9/26/11 FROM OSI
2013-4872	06/25/2013 07/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	WOODS 10-D-2776, LEON	PIROXICAIN - AER
2013-4873	06/26/2013 07/25/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	LIPOID, GERMANY - EIR 2011
2013-4874	06/26/2013	FDA/OMPT/CBER/OCOD/DDOM/		INDIVIDUAL RECS

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	07/25/2013	ALFB/ FDA/OC/OES/DFOI/	Doe J	
2013-4875	06/26/2013 07/25/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	Catherine Templeton for Henry H. Ottens Manufacturing Company, Inc. Henry H. Ottens Manufacturing Company, Inc.	HENRY H OTTENS MANUFACTURING COMPANY, PHILADELPHIA, PA - EIR REDACTED (05/01/2012 - 06/20/2013)
2013-4876	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	LIPOID, GERMANY - EIR SUMMARY 2011
2013-4877	06/26/2013 07/25/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS (05/19/2013 - 06/21/2013)
2013-4878	06/26/2013 07/25/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	Tony L. Bennett ENCO Pharmaceutical Development, Inc.	ENCO PHARMACEUTICALS DEVELOPMENT, CARY, NC; JACKSONVILLE, FL - PUBLIC RECS (01/01/2005 - 06/21/2013)
2013-4879	06/26/2013 07/25/2013	CVM/OCD/	Bert Baker Zoetis Inc.	NADA 120-299 FOIA SUMMARY
2013-4880	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	BLA 125166 - FOIA REQUESTS
2013-4881	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125166
2013-4882	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Douglas Fulton Crystal Bay Consulting	K080145, K083352
2013-4883	06/26/2013 07/25/2013	FDA/OC/OES/DDM/	Freddy Mejia Ansell Healthcare Products LLC	DKT 75N-0183
2013-4884	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/3-7/13
2013-4885	06/26/2013 07/25/2013	FDA/OF/CFSAN/OCD/EOS/	PAULINA DO EXPONENT	GRAS 000037
2013-4886	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN BEEKMAN ALCON LABORATORIES INC	EXCELVISION, CEDEX, FRANCE - 483 2012

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2013-4887	06/26/2013 07/25/2013	FDA/OO/OHR/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	LORRAINE PHILIPPS AMABILE & ERMAN PC	INDIVIDUAL RECS
2013-4888	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DODGE, ALLENE M	VIVOTROL (NALTRXENE ER INJECTABLE SUSPENSION) NDA 21-897/S015 - SBA
2013-4889	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AYA ABOUNASR UNIV OF CALIFORNIA SAN FRANCISCO	CLEMASTINE FUMARATE NDA 73-283 - TOXICITY TESTS, AERS, MEDICAL RVWS, ETC
2013-4890	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AYA ABOUNASR UNIV OF CALIFORNIA SAN FRANCISCO	TAVIST TABS NDA 17-661 - AERS, TOXICITY TESTS, MEDICAL RVWS, ETC
2013-4891	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/3-7/13
2013-4892	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 6/3-7/13
2013-4893	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/3-7/13
2013-4894	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/3-7/13
2013-4895	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/27-31/13
2013-4896	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/27-31/13
2013-4897	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/27-31/13
2013-4898	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 5/27-31/13

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2013-4899	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/27-31/13
2013-4900	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRMAP CanReg, Inc.	FOI DAILY LOG 5/20-24/13
2013-4901	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 5/20-24/13
2013-4902	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/20-24/13
2013-4903	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 5/20-24/13
2013-4904	06/26/2013 07/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/20-24/13
2013-4905	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K 70065 REVIEWER DECISION NOTES
2013-4906	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K080185 REVIEWER DECISION NOTES
2013-4907	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K040623 REVIEWER DECISION NOTES
2013-4908	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC - K040537 REVIEWER DECISION NOTES
2013-4909	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KATHRYN A. PRYOR, Esq. SIMON GREENSTONE ET AL	IBUPROFEN - AER 2/12 TO 6/13
2013-4910	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KILPATRICK, PETER	DJO LLC - EMPI PHOENIX K124016
2013-4911	06/26/2013 07/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FRIEDMAN, ROBERT.	CHILDRENS MOTRIN SUSPENSION LIQUID - FAERS 1969 TO 2013

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2013-4912	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL J. GLIDDEN, Esq. PEREZ AND MORRIS LLC	KENALOG (TRIAMCINOLONE ACETONIDE) EFFICACY
2013-4913	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	OLE ALEKSANDER BERG CHITINOR	DMF 19244; 19245; 19246
2013-4914	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ABOUNASR, AYA	CLEMASTINE FUMARATE - NDA, AER, MEDICAL RVWS
2013-4915	06/26/2013 07/25/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OC/OES/DFOI/	TURNER, ERWIN LLOYD	CMPLNT 121322
2013-4916	06/26/2013 07/25/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	KATHY CONACHER DRAGER MEDICAL INC	DRAEGER MEDICAL INC - EIR 6/29-7/9/09
2013-4917	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAN RICE DAVID HEALTH SOLUTIONS	K952163, FEI 3009507304 8/12/96
2013-4918	06/26/2013 07/25/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AARON S. JOPHLIN BELL LEGAL GROUP LLC	DR. GREGORY GARDZIOLA, SOUTH CAROLINA - INFO
2013-4919	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	VICTORIA CHERRIMAN BODYWISE LTD	BODYWISE LTD - ALMONDSBURY, BRISTOL NATRACARE TAMPON K954942
2013-4920	06/26/2013 07/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T. FOWLER REED SMITH LLP	AMERICAN MEDICAL SYS INC K033636 - REVIEWER DECISION NOTES
2013-4921	06/26/2013 07/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MATTHEW K. SCHWENCKE SEARCY DENNEY ET AL	NITROFURANTOIN; MACRODANTIN; MACROBID - WARINGS, LBLG, EFFICACY 2001 TO 2008

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4922	06/26/2013 07/25/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	DANIEL W. ERNSBERGER BEHREND & ERNSBERGER PC	SMITH & NEPHEW - VISIONAIRE KNEE REPLACEMENT AER
2013-4923	06/27/2013 07/26/2013	FDA/OF/CFSAN/OCD/EOS/	Todd Rogers Clipper Corporation	KAIRUM CO, LIMITED, FUJIAN, CHINA - INSPECTION RECS (01/23/2010 - 06/26/2013)
2013-4924	06/27/2013 07/26/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Ethan Lovell JANUS CAPITAL GROUP INC	QUALITEST/VINTAGE PHARMACEUTICALS, HUNTSVILLE, AL - EIR (01/01/2010 - 09/30/2013)
2013-4925	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Victoria Cherriman Bodywise (UK) Ltd	K954942 - REGISTRATION CONFIRMATION
2013-4926	06/27/2013 07/26/2013	CVM/OCD/	Nancy Agan Nancy Agan	LANTUS - AERS
2013-4927	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Melvyn Harris Dr. Melvyn Harris	ULTRAM, ULTRACET - RECS RE WARNING CHANGE
2013-4928	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102512
2013-4929	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Arlene D Ast Ast , Arlene D	DARVOCET - STUDY OF CARDIAC TOXICITY, REMOVAL FROM MARKET
2013-4930	06/27/2013 07/26/2013	FDA/OF/CFSAN/OCD/EOS/	Jim Huang Bemis Company, Inc.	FCN 123, 349, 413 ETC - CHEMISTRY MEMORANDA
2013-4931	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dawn Spark ProStrakan Limited	NDA 019926 - SBA
2013-4932	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carter Gould JMP Securities	ADCETRIS - AERS
2013-4933	06/27/2013	FDA/OMPT/CTP/OD/	Stacy Jones	ELECTRONIC CIGARETTES, E-LIQUIDS, ACCESSORIES - AERS

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	07/26/2013		The Star-Ledger	
2013-4934	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	NV SUMATRA - NEW TOBACCO PRODUCT SUBMISSIONS
2013-4935	06/27/2013 07/26/2013	FDA/OF/CFSAN/OCD/EOS/	Elaine Meloan AIB International	RESCISSION LETTER FROM CFSAN TO CLAUSEN ELY OR CORN REFINERS ASSOCIATION (01/28/2010 - 06/21/2013)
2013-4936	06/27/2013 07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chris Patullo Long Pharmaceuticals, LLC	TRIAMCINOLONE ACETONIDE, 0.1% PASTE - APPROVAL LETTERS, ADMIN RECS, BIOEQUIVALENCE REVIEWS, ETC
2013-4937	06/27/2013 07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Frederick Nielson Nellis AFB Family Medicine Residency	METHYLSULFONYLMETHANE - AERS
2013-4938	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	John Shoemaker Visium	FOUR NSE ORDERS DISCLOSED JUNE 25, 2013 FROM CTP
2013-4939	06/27/2013 07/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO PRODUCT AERS
2013-4940	06/27/2013 07/26/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Farah Awan AUROBINDO PHARMA USA INC	TESTING RESULTS
2013-4941	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Boston Scientific 510(k) #K121048 Anna Christensen Consulting	K121048
2013-4942	06/27/2013 07/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Seongsoo Park DAEWOONG AMERICA INC	ACTIGALL - EXPIRATION DATE CHANGE
2013-4943	06/27/2013 07/26/2013	FDA/OC/OES/ FDA/OMPT/CDRH/OCER/DFOI/	Mark McCarty Medical Device Daily	INTERNAL RECS RE ALVARO PASCUAL-LEONE AND 2/10/12 MEETING OF NEUROLOGICAL DEVICES ADVISORY COMMITTEE
2013-4944	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 5/13-17/13
2013-4945	06/27/2013	FDA/OC/OES/DFOI/	BARBARA JONES	FOI DAILY LOG 5/13-17/13

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	07/26/2013		DOMINION GROUP INC	
2013-4946	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 5/13-17/13
2013-4947	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	GLADYS SB TONKIN Center for Regulatory Services, Inc.	FOI DAILY LOG 5/13-17/13
2013-4948	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	KEN REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 5/13-17/13
2013-4949	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/3-7/13
2013-4950	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/27-31/13
2013-4951	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/20-24/13
2013-4952	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 5/13-17/13
2013-4953	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 6/3-7/13
2013-4954	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/27-31/13
2013-4955	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/20-24/13
2013-4956	06/27/2013 07/26/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	FOI DAILY LOG 5/13-17/13
2013-4957	06/27/2013 07/26/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TORREY COPE SIDLEY AUSTIN LLP	AKORN INC - PHENYLEPHRIN EHCL OPTHALMIC SOL USP WARNING LTR COMM 3/29/07 TO PRESENT
2013-4958	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAULSON & NACE	ABBOTT LABS - HUMIRA POST-APRVL SAFETY STUDIES; TREXALL, RHEUMATREX (METHOTREXATE) AERS 1998 TO 2012, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-4959	06/27/2013 07/26/2013	FDA/OGROP/ORP/NE-FO/NYK-DO/NYK-DCB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORP/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORP/SE-FO/NOL-DO/NOL-CB/	NICHOLAS PARALISI DIETRICH LAW FIRM PC	RICH PRODUCTS -STAIN O121 OUTBREAK INVESTIGATION, RECALL, RECS
2013-4960	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JENNIFER LAWRENCE ESQ LAWRENCE FIRM	INTUITIVE SURGICAL INC - DA VINCI SURGICAL SYS K130726, K122532, K123840, ETC
2013-4961	06/27/2013 07/26/2013	FDA/OO/OHR/	Doe J	PERSONNEL RECS
2013-4962	06/27/2013 07/26/2013	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	DKT 2011N-0867
2013-4963	06/27/2013 07/26/2013	FDA/OO/OFBA/OAGS/	ZAHRA SHAH Singhal & Company, Inc.	#HHSF2232008300141
2013-4964	06/27/2013 07/26/2013	FDA/OO/OFBA/OAGS/	NATHAN A BEAVER FOLEY & LARDNER LLP	GRANT DEVELOPMENT OF BIO-RELEVANT IN-VITRO ASSAY TO DETERMINE LABILE IRON IN THE PARENTERAL IRON COMPLEX PRODUCT - INDIVIDUALS WHO SUBMITTED GRANT REQUESTS, APPL
2013-4965	06/27/2013 07/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID HOFFMEISTER WILSON SONSINI ET AL	ADVAIR NDA 21-077/S050 - SBA
2013-4966	06/27/2013 07/26/2013	FDA/OF/CFSAN/OCD/EOS/	MAREN R CAVE SWIFT CURRIE MCGHEE & HIRS	SALMONELLA SEROTYPE TENNESSEE - SURVEILLANCE DATA 2011
2013-4967	06/27/2013 07/26/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CHRISTA C COTTRELL KIRKLAND & ELLIS LLP	PLASMA PROTEIN THERAPEUTICS ASSN - PLASMA-DERIVED PROTEIN THERAPIES (PDPT) RECS, CORR 1998 TO 2010
2013-4968	06/27/2013 08/12/2013	FDA/OF/CFSAN/OCD/EOS/	MITZI NG CLARK Keller and Heckman LLP	FCN 1266
2013-4969	06/27/2013 08/12/2013	FDA/OMPT/CTP/OD/ FDA/OMPT/CTP/OD/	JOEL KURTZBERG CAHILL GORDON & REINDEL	EXPERIMENTAL STUDY OF GRAPHIC CIGARETTE WARNING LABELS - DRAFTS, ANALYSIS, COMM, ETC

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		FDA/OC/OES/DFOI/		
2013-4970	06/27/2013 07/26/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	RANDALL S HAYNES MORRIS HAYNES & HORNSBY	LIFESOUTH COMMUNITY BLOOD CENTERS INC - INSP EXHIBITS 11/11
2013-4971	06/27/2013 07/26/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	RANDALL S HAYNES MORRIS HAYNES & HORNSBY	EAST ALABAMA MEDICAL CENTER, LIFESOUTH COMMUNITY BLOOD CENTERS INC - EIRS, 483S, CORR, ETC
2013-4972	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	RICHARD A BASLER MED-VISORY CONSULTING INC	SMITH MEDICAL - MEDFUSION 400 INFUSION PUMP K111386
2013-4973	06/27/2013 07/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANKE WEISBRICH SENTEC AG	DVC MASTER FILE MAF 1176
2013-4974	06/27/2013 07/26/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	EXPRESS FREIGHT INTL - ENTRY #AL600480928 NOTICES FOR REQUEST OF INFORMATION, NOTICES OF ACTION, CBP REDELIVER NOTICES, ETC
2013-4975	06/27/2013 07/26/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 5/1-31/13
2013-4976	06/28/2013 07/29/2013	FDA/OC/OES/DDM/	GEORGE O'BRIEN HOGAN LOVELLS LLP	DKT FDA-2013-P-0058, FDA-2013-P-0119, ETC.
2013-4977	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michael Higgins Highline Research Advisors	HUMALOG, NOVOLOG, EXUBERA - AERS
2013-4978	06/28/2013 07/29/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT DETERMINATION FOR GF1200548
2013-4979	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy Bassett Pura Vida Investments	DIMETHYL FUMARATE - 9284739 9292048 9304601 ETC
2013-4980	06/28/2013 07/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	bob taylor bob taylor	CHURCH OF JESUS CHRIST OF LATTER-DAY SAINTS DRY PACK CANNING FACILITY, BREMERTON, WA - INSPECTION REPORTS (06/01/2008 - 06/01/2011)

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		FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/		
2013-4981	06/28/2013 07/29/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2012-6315
2013-4982	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING CANCELLOUS CHIPS; CUBES K051615
2013-4983	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - BIOSET XC K060180
2013-4984	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW HT K052405
2013-4985	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - BIOSET XC K060180
2013-4986	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGNERATION TECHNOLOGIES INC - STERLING CANCELLOS CHIPS; CUBES K051615
2013-4987	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW HT K052405
2013-4988	06/28/2013 07/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	MUJIB GRIFOLS BIOLOGICALS INC	CSL BEHRING, BERN SWITZERLAND - 483, EIR 1/10 TO 12/12
2013-4989	06/28/2013 07/29/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JANNA dePORT NC INTEGRATIVE MEDICAL SOCIETY	HCG - AER
2013-4990	06/28/2013 07/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JENNIFER HSIEH DEERFIELD INSTITUTE	SEATTLE GENETICS - ADCETRIS (BRENTUXIMAB VEDOTIN) AER
2013-4991	06/28/2013 07/29/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WEINBERG, SANFORD .	CMPLNT 131562
2013-4992	06/28/2013 07/29/2013	FDA/OF/CFSAN/OCD/EOS/	JANNA dePORTER CENTER FOR SCIENCE IN THE PUBLIC INTEREST	RHM RESEARCH ENGLAND - MYCOP (MYCELIUM FUSARIUM GRAMINEARUM) FAP

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2013-4993	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW ST K050767
2013-4994	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	LATANIA BLACK MEDTRONIC	REGENERATION TECHNOLOGIES INC - STERLING INTERFERENCE SCREW ST K050767
2013-4995	06/28/2013 07/29/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	K. MICHELLE VASSALLO LINCARE INC	NEW ENGLAND LIFE CARE, SOUTH PORTLAND, ME - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-4996	06/28/2013 07/29/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	LOCKE 2540578 2 LEFT, EDWARD	BRISTOL MYERS SQUIBB - COUMADIN BLACK BOX WARNING
2013-4997	06/28/2013 07/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANTHONY PAVEL MORGAN LEWIS	IRVINE SCIENTIFIC SALES CO INC - CONTINUOUS SINGLE CULTURE COMPLETE K121572
2013-4998	06/28/2013 07/29/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WASHINGTON, PAMELA	CMPLNT 128812
2013-4999	06/28/2013 07/29/2013	FDA/OF/CFSAN/OCD/EOS/	ROBERT K REIMANN JAMES E FREEMYER PC	E COLI OUTBREAK 9/09 TO PRESENT
2013-5000	06/28/2013 07/29/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	ROOPAL P. LUHANA CHAFFIN LUHANA LLP	SMITH & NEPHEW INC - R3 ACETABULAR SYS CMPLNTS, INVESTIGATIONS, RECALLS
2013-5001	06/28/2013 07/29/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	TURNER, ERWIN LLOYD	CMPLNT 121322
2013-5002	06/28/2013 07/29/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	ANDERSON 605229, PERCY	MORBIC MELOXICAM; DIURETIC HYDROCHLOROTHIAZIDE - AER
2013-5003	06/28/2013 07/29/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	GILL, DAVID A	NATURA PET PRODUCTS - SALMONELLA INFO
2013-5004	06/28/2013	FDA/OMPT/CDER/ERP/DIDP/		CITALOPRAM - AER

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	07/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	
2013-5005	06/28/2013 07/29/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELWOOD, JOHNNA	ZOFTRAN - AER
2013-5006	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	James Simmons Alamo Bone and Joint Clinic	K071833
2013-5007	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Brian Brockway VivaQuant, LLC	K103764 ,K081444, K092947 ETC
2013-5008	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Barbara B. Perkins not applicable	K872369 - PREDICATE DEVICE
2013-5009	07/01/2013 07/30/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Brent Ardaugh Framingham Heart Study	HEART-AID MODEL 60 EXTERNAL DEFIBRILLATOR - RECALL RECS
2013-5010	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie A. Richards Manning Curtis Bradshaw & Bednar	K020086
2013-5011	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102258
2013-5012	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101561
2013-5013	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K021989
2013-5014	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Miller Flared Medical LLC	K941299
2013-5015	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	510K number K123169 OralID, Forward Science LLC Gross, Richard	K123169
2013-5016	07/01/2013 07/30/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ELECTRONIC CIGARETTES - AERS
2013-5017	07/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ariel Dora Stern	NONAPPROVED PMA DATA

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	07/30/2013		NATIONAL BUREAU OF ECONOMIC RESEARCH	
2013-5018	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Florence Bourgeois Boston Children's Hospital Informatics Program	CYLERT, ADDERALL, DEXEDRINE ETC - PIVOTAL EFFICACY AND SAFETY CLINICAL TRIAL DATA
2013-5019	07/01/2013 07/30/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	RUDY ORTIZ WAWONA PACKING COMPANY LLC	PESTICIDE RESIDUE SAMPLE NUMBER 800343
2013-5020	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Deanna Hunt Self	K073111
2013-5021	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Changaris Ceela Naturals	SALICYCLIC ACID - CURRENTLY LISTED MANUFACTURERS
2013-5022	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Patricia Kime Gannett Government Media, Inc	ISR 8274421
2013-5023	07/01/2013 07/30/2013	FDA/OF/CFSAN/OCD/EOS/	Monica Engebretson Cruelty Free International	COSMETICS SAFETY TESTS
2013-5024	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Virginia Baker NA	ARICEPT, NAMENDA - AERS
2013-5025	07/01/2013 07/30/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Mike Conley The McDowell News	BAXTER INTERNATIONAL, MARION, NC - RESPONSE TO WARNING LETTER
2013-5026	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mondira Bhattacharya AbbVie, Inc.	915 COMPREHENSIVE REVIEW OF ANDROGEL 1.62%

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2013-5027	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Amy Gonzales AMGEN INC.	MUSTAFA NEVZAT PHARMACEUTICALS, ISTANBUL, TURKEY - EIR 05/02/2012 - 05/30/2013
2013-5028	07/01/2013 07/30/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ ORA/OCI/ ORA/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - MINS OF MEETINGS, NOTES, WARNING LTRS, ETC
2013-5029	07/01/2013 07/30/2013	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - WORLD HEALTH ORGANISATION COMM, RPT, ETC 2004
2013-5030	07/01/2013 07/30/2013	FDA/OC/OES/DFOI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - INVESTIGATIONS 1/05 TO PRESENT
2013-5031	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ ORA/OCI/ ORA/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - INVESTIGATION CORR
2013-5032	07/01/2013 07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/ ORA/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) DAIICHI SANKYO COMPANY LTD NEGOTIATIONS , RPTS INTERNAL, EXTERNAL

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		ORA/OCI/		
2013-5033	07/01/2013 07/30/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LOBORATORIES LTD (RANBAXY) - DINESH THAKUR OR RAJINDER KUMAR, RPTS, EMAIL, ETC 2004
2013-5034	07/01/2013 07/30/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - DEWAS FACILITIES EIRS, 483S1/28/08-2/12/08, OHM LABS, GLOVERSVILLE FACILITY 7/13/09-8/12/09, ETC
2013-5035	07/01/2013 07/30/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ OC/OCC/ ORA/OCI/ ORA/OCI/	PAULA RAMER KAYE SCHOLER LLP	RANBAXY USA INC, RANBAXY LABORATORIES LTD (RANBAXY) - DINESH THAKUR, RAJINDER COMM, AUDIT RPT, ETC 2004
2013-5036	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	PLATSKY, HENRY	INDIVIDUAL RECS
2013-5037	07/01/2013 07/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	BENJAMIN LL ENGLAND BENJAMIN L ENGLAND & ASSOCIATES LLC	SILVERLON - CONTAC WOUND DRESSING K991463; SILVERLONE DIRECT PRESSURE WOUND CLOSURE STRIP K984204; SILVERLON DIRECT PRESSURE WOUND DRESSING K984207, ETC
2013-5038	07/01/2013 07/30/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	JOANNE S HAWANA ARENT FOX LLP	ORA VERSES INJ OR PHENTWOLAMINE MESYLATE - ISRS 8247773, 7897322
2013-5039	07/01/2013 07/30/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	ALESHIRE 278999, DAVID .	ROXISCT 30 MG; SOBOXEN - AERS
2013-5040	07/01/2013	FDA/OMPT/CDER/ERP/DIDP/	PAULA RAMER	RANBAXY USA INC, RANBAXY LABORATORIES LTD

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	07/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/	KAYE SCHOLER LLP	(RANBAXY) - DAIICHI SANKYO COMPANY LTD CORR, INTERVIEWS, MEETINGS, ETC 2004
2013-5041	07/01/2013 07/30/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	DOUGLAS N BLUE ZETETIC	SIMILAC, ENFAMIL INFANT FORMULA ENTRY NUMBER DP4- 062812-8 PHOTOGRAPHS, OASIS COMPUTER DATA BASE SCREEN SHOTS
2013-5042	07/01/2013 07/30/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	J KENT LOWRY ARMSTRONG TEASDALE LLP	NATURAL PET PRODUCTS INC - SALMONELLA INVESTIGATION RPTS, ADMINISTRATIVE SANCTIONS 3/19/13 TO PRESENT
2013-5043	07/01/2013 07/30/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	COLEN GRACE DONOFRIO BABST/CALLAND	GILES CHEMICAL (PREMIER CHEMICALS LLC), WAYNESVILLE, NC - EIRS 8/2/12
2013-5044	07/01/2013 07/30/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ ORA/ ORA/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	CHRISTINE RAMETTE SURETY CLAIMS INC	ENTRY NUMBER BPX-0001405-6
2013-5045	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Nadeau Covidien llc	K926118 - SUMMARY LETTER
2013-5046	07/02/2013 07/31/2013	FDA/OMPT/OSMP/OOPD/	Lauren A. Farruggia Hyman, Phelps & McNamara, P.C.	PROCYSBI - ORPHAN DRUG DESIGNATION FILE
2013-5047	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	Megan Pickel BEVERIDGE & DIAMOND	CFSAN FOIA REQUESTS 06/07/2013 TO 07/01/2013
2013-5048	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alexis McKenzie Key Tech	BAXA CORPORATION EXACTA-MIX 2400 510K SUMMARY
2013-5049	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robert Wick Tosoh Bioscience, Inc.	K12129 - 510K SUMMARY
2013-5050	07/02/2013 07/31/2013	FDA/OF/CFSAN/OCD/EOS/ CVM/OCD/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	ENSURE - AERS
2013-5051	07/02/2013 07/31/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	SLIM FAST - AERS

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2013-5052	07/02/2013 07/31/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	DAVOL BARD MESH PERFIX PLUS LARGE MONAFILAMENT KNITTED POLYPROPYLENE - RECALL RECS (09/01/2003 - 06/28/2013)
2013-5053	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephanie A. Richards Manning Curtis Bradshaw & Bednar	DYNAMIC COMPRESSION SHAPE MEMORY ALLOY STAPLE - IDE
2013-5054	07/02/2013 07/31/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Pete Kennedy Pete Kennedy	DAIRY OF THE OZARKS, LLC - CORR, EMAIL, AGREEMENTS ETC (06/01/2013 - 05/15/2013)
2013-5055	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Nadeau Covidien llc	K802286 - 510K SUMMARY
2013-5056	07/02/2013 07/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hong Luo HARVARD BUSINESS SCHOOL	NDA, ANDA APPROVALS 01/01/1980 - 06/01/2013
2013-5057	07/02/2013 07/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lori Franson Lori Franson, Individual	ZYPREXA RELPREV
2013-5058	07/02/2013 07/31/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Vince Calhoun UNIVERSITY OF NEW MEXICO	UNM HEALTH SCIENCE CENTER IRB - EIR (05/01/2013 - 08/01/2013)
2013-5059	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-3989
2013-5060	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELLEN RELKIN ESQ WEITZ & LUXEMBERG PC	BIOMET INC - RECAP FEMORAL RESURFACING SYS MDRS, MEMOS, CLNCL TRIALS, ETC
2013-5061	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/OC/OCC/	LOUISE N HOWE GOODWIN PROCTER LLP	CARDIOVASCULAR INTRAVASCULAR FILTERS - RECLASSIFICATION FROM CLASS III TO CLASS II
2013-5062	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	CARLA R SCARMAZZI King & Spalding LLP	INTUITIVE SURGICAL, SUNNYVALE, CA - 483S 1/103 TO PRESENT
2013-5063	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2011-6067, 2011-7185, 2011-7361, ETC

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2013-5064	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2009-1630, 2009-1631, 2009-1645, ETC
2013-5065	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-7775, 2012-5883, 2012-7797, ETC
2013-5066	07/02/2013 07/31/2013	FDA/OC/OES/DDM/	WILLIAM C WHITE II PARKMAN & WHITE LLC	GUIDANCE FOR INDUSTRY TESTING FOR SALMONELLA SPECIES IN HUMAN FOODS AND DIRECT-HUMAN-CONTACT ANIMAL FOODS
2013-5067	07/02/2013 07/31/2013	CVM/OCD/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	NEW AAFCO FEED INGREDIENT DEFINITION FOR DEOILED DISTILLERS PRODS
2013-5068	07/02/2013 07/31/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KAREN COLLINS HARDISON COCHRAN	MIRENA - MDRS 1/08 TO PRESENT
2013-5069	07/02/2013 09/17/2013	ORA/ ORA/	JAMES, AL	INDIVIDUAL RECS 4/13 TO 6/13
2013-5070	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	ANDREW HACK MD PHD MILLENNIUM MANAGEMENT LLC	2013-2551, 2013-2466, 2013-2321, ETC
2013-5071	07/02/2013 07/31/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AYA ABOUNASR UNIV OF CALIFORNIA	CLEMASTINE FUMARATE TABS ANDA 73-283, ANDA 73-458; TAVIST-1 NDA 17-661, NDA 20-925 APRVL RECS, AERS 1997 TO PRESENT
2013-5072	07/02/2013 07/31/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2013-4343
2013-5073	07/03/2013 08/01/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Caroline Unger Central Texas Regional Blood and Tissue Center	BACTERIN INTERNATIONAL, INC - 483, RESPONSE TO 483, RESPONSE TO WARNING LETTER, ETC (07/16/2012 - 07/01/2013)
2013-5074	07/03/2013 08/01/2013	FDA/OMPT/CTP/OD/	Anna Edney BLOOMBERG NEWS	COMPANIES AND PRODUCTS ISSUED A NON SUBSTANTIALLY EQUIVALENT ORDER FROM CTP; SUBSTANTIALLY EQUIVALENT AND NOT SUBSTANTIALLY EQUIVALENT ORDERS
2013-5075	07/03/2013 08/01/2013	FDA/OMPT/OSMP/OOPD/	Sharon Sakai Adamas Pharmaceuticals	APOMORPHINE - ORPHAN DRUG DESIGNATION
2013-5076	07/03/2013 08/01/2013	ORA/ORM/ ORA/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES ISSUED FORM 483 05/13/2013 - 06/30/2013

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2013-5077	07/03/2013 08/01/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Victor Martinez Victor Martinez	FOOD BANK OF THE RIO GRANDE VALLEY, INC, PHARR, TEXAS - INSPECTIONS, TESTING, COMMUNICATIONS
2013-5078	07/03/2013 08/01/2013	CVM/OCD/	Paul K. Mignon Mignon, Paul K	ANADA 200-168 AMENDMENTS
2013-5079	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Nadeau Covidien llc	K810216 - SUMMARY LETTER
2013-5080	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carrie Gray Phillips Law Group PLLC	ST JUDE MEDICAL - ADVERSE EVENT RECS
2013-5081	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED AND RELEASED JUNE 2013
2013-5082	07/03/2013 08/01/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Marion McNeilly Annies Marlborough Ltd	442-0762268-7 35898052 - TEST RESULTS
2013-5083	07/03/2013 08/01/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	IOPIDINE - SBA
2013-5084	07/03/2013 08/01/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Ashley Yeager The Simon Law Firm	ISR 6749253, 6776928, 6809862 ETC
2013-5085	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ ORA/OCI/ ORA/OCI/	Heather M. McKinney Renaud Cook Drury Mesaros, PA	TRIAD GROUP, H&P INDUSTRIES, EDGE PARK MEDICAL SUPPLIES ETC - INVESTIGATION RECS

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2013-5086	07/03/2013 08/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	C. Gansen GANSEN LAW GROUP	ADVATE - CASE REPORTS
2013-5087	07/03/2013 08/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	CDER OSI RECORDS RE C1639 BETWEEN 12/7/2006 AND 1/15/2007
2013-5088	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA LOG 6/24/2013 TO 6/28/2013
2013-5089	07/03/2013 08/01/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Julie Quick BioLife Plasma Services L.P.	QUALTEX LABORATORY, NORCROSS, GA - EIR (01/01/2009 - 07/01/2013)
2013-5090	07/03/2013 08/01/2013	FDA/OC/OES/	Anna Edney BLOOMBERG NEWS	EMAIL, CORR BETWEEN MARGARET HAMBURG AND LEONA BRENNER-GATI
2013-5091	07/03/2013 08/01/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JESSICA QUIASON 1199 SEIU	BRIGHAM & WOMENS HOSPITAL, MCLEAN HOSPITAL, MASSACHUSETTS GENERAL HOSPITAL, ETC - INFORMED CONSENT ISSUES COMM
2013-5092	07/03/2013 08/01/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Doe J	INDIVIDUAL RECS
2013-5093	07/03/2013 08/01/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	KYPROLIS (CARFILZOMIB) - FAERS 1/12 TO PRESENT
2013-5094	07/03/2013 08/01/2013	FDA/OC/OES/DDM/	SAMANTHA HERBERT GOODWIN PROCTER LLP	DKT FDA-2013-N-0234
2013-5095	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD A. MONTAGNA, Ph.D. RHEONIX	LUMINEX MOLECULAR DIAGNOSTICS, ONTARIO, CANADA - XTAG GASTROINTESTINAL PATHOGEN PANEL (GPP) K121894
2013-5096	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	MINA KIMES BLOOMBERG NEWS	CYBER SECURITY INCIDENTS IMPACTING MEDICAL DVC MFRS, HOSPITALS, USERS, ETC LAST 24 MONTHS
2013-5097	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	MINA KIMES BLOOMBERG NEWS	CYBER SECURITY VULNERABILITIES COMM LAST 24 MONTHS
2013-5098	07/03/2013 08/01/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDA NEWS	MEDICAL DVC MANUFACTURING, CLNCL TRIAL FACILITIES - 483 6/1-30/13

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2013-5099	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/	BURTON, JOHN M	CASE # PH 044016
2013-5100	07/03/2013 08/01/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PLX PHARMA - ASPIRIN NDA 203-697 LBLG
2013-5101	07/03/2013 08/01/2013	FDA/OGROP/ORAP/FO/SEA-DO/SEA-CB/	JAMES A. PERKINS LARSON BERG ET AL	INDIVIDUAL RECS
2013-5102	07/03/2013 08/13/2013	FDA/OMPT/CTP/OD/	AZIM CHOWDHURY Keller and Heckman LLP	LORILLARD TOBACCO CO - NEWPORT NON MENTHOL GOLD BOX 100 SUSTAINABLE EQUIVALENCE RPTS
2013-5103	07/03/2013 08/15/2013	FDA/OF/CFSAN/OCD/EOS/	PAULINA DO EXPONENT	SAINT GOBAIN ADVANCED CERAMICS CORP - BORON NITRIDE FCN 289; COLOR MATRIX GROUP - SODIUM BOROHYDRIDE FCN 1224; TOTAL LUBRIFIANTS - CALCIUM BORATE FCN 1189
2013-5104	07/03/2013 08/01/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2011-4942; 2011-5064, 2011-9169 ETC
2013-5105	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD A. MONTAGNA, Ph.D. RHEONIX	BIOFIRE DIAGNOSTICS, SALT LAKE CITY, UT - FILM ARRAY BLOOD CULTURE IDENTIFICATION (BCID) PANEL K130914
2013-5106	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD A. MONTAGNA, Ph.D. RHEONIX	LUMINEX MOLECULAR DIAGNOSTICS, TORONTO, ONTARIO - X TAG GASTROINTESTINAL PATHOGEN PANEL (GPP) K121454
2013-5107	07/03/2013 08/01/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	EXPANDED ACCESS TO INVESTIGATIONAL DRUGS REQUESTS 6/1/12
2013-5108	07/03/2013 08/01/2013	FDA/OMPT/CDRH/OCER/DFOI/	NICKI M. McDONALD BLASKE AND BLASKE PLC	VASCUTEK LTD - GELWEAVE DVC PROTHESIS RECS
2013-5109	07/03/2013 08/01/2013	FDA/OGROP/ORAP/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORAP/FO/SEA-DO/SEA-CB/	K. MICHELLE VASSALLO LINCARE INC	ADVENTIST MEDICAL EQUIPMENT, PORTLAND, OR - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-5110	07/03/2013 08/15/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/ ORA/	MATTHEW C. MOEHLMAN LABATON SUCHAROW	YUM BRANDS INC - CHEMICAL CONTAMINANTS IN POULTRY SUPPLIED TO THE CHINESE BUSINESS SEGMENT OF KFC

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		ORA/ ORA/ ORA/		
2013-5111	07/05/2013 08/02/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKELY THOMSON REUTERS	EXEMPLAR LABORATORIES LLC, FALL RIVER, MA - EIRS, 483S, CO RESP 1/13/12
2013-5112	07/05/2013 08/02/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	ELI LILLY & CO, INDIANAPOLIS, IN - EIRS, 483S, CO RESP 12/14/12
2013-5113	07/05/2013 08/02/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	EISAI INC, WOODCLIFF LAKE, NJ - EIRS, 483S, CO RESP 1/17/13
2013-5114	07/05/2013 08/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DYNAVAX TECHNOLOGIES CORP, BERKELEY, CA - EIRS, 483S, CO RESP 10/17/12
2013-5115	07/05/2013 08/02/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHILDREN'S HOSPITAL RESEARCH CENTER OAKLAND, OAKLAND, CA - EIRS, 483S, CO RESP 1/09/13
2013-5116	07/05/2013 08/02/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOGEN IDEC INC, CAMBRIDGE, MA - EIRS, 483S, CO RESP 3/15/13
2013-5117	07/05/2013 08/02/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO-BLOOD COMPONENTS INC, GARY, IN - EIRS, 483S, CO RESP 1/14/13
2013-5118	07/05/2013 08/02/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BENAROYA RESEARCH INSTITUTE, SEATTLE, WA - EIRS, 483S, CO RESP 1/29/13
2013-5119	07/05/2013 08/02/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	AKORN INC, SOMERSET, NJ - EIRS, 483S, CO RESP 2/01/13
2013-5120	07/05/2013 08/02/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	VETERANS ADMINISTRATION MEDICAL CENTER, BOISE, ID - EIRS, 483S CO RESP 1/24/13
2013-5121	07/05/2013 08/02/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROBERT J SHULMAN, HOUSTON, TX - EIRS, 483S, CO RESP 5/09/12
2013-5122	07/05/2013 08/02/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DIANE J NUGENT MD, ORANGE, CA - EIRS, 483S, CO RESP 6/22/12
2013-5123	07/05/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS VACCINES & DIAGNOSTICS GMBH & CO, KG, MARBURG, GERMANY - EIRS, 483S, CO RESP 7/17/12
2013-5124	07/05/2013 10/08/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LAS CRUCES BIOLOGICALS LLC, LAS CURCES, NM - EIRS, 483S, CO RESP 2/13/13
2013-5125	07/05/2013	FDA/OGROP/ORA/SW-FO/DAL-	WALTER E CHALKLEY	MICHAEL T JARRATT MD, AUSTIN, TX - EIRS, 483S, CO

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	08/02/2013	DO/DAL-CB/	THOMSON REUTERS	RESP 6/21/12
2013-5126	07/05/2013 10/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	INNOVASIC INC, SALT LAKE CITY, UT - EIRS, 483S, CO RESP 4/27/12
2013-5127	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	IBA MOLECULAR, STERLING, VA - EIRS, 483S, CO RESP 2/01/13
2013-5128	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	GE HEALTHCARE, MEDICAL DIAGNOSTICS, PRINCETON, NJ - EIRS, 483S, CO RESP 8/20/12
2013-5129	07/05/2013 08/02/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CUMBERLAND PHARMACEUTICALS INC, NASHVILLE, TN - EIRS, 483S, CO RESP 4/04/12
2013-5130	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAPRICORN PHARMA INC, FREDERICK, MD - EIR, 483S, CO RESP 3/04/13
2013-5131	07/05/2013 08/02/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIO-CONCEPT LABORATORIES INC, SALEM, NH - EIRS, 483S, CO RESP 1/10/13
2013-5132	07/05/2013 08/02/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	AVIOQ INC, RESEARCH TRIANGLE PARK, NC - EIRS, 483S, CO RESP 2/08/13
2013-5133	07/05/2013 08/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	AUROBINDO PHARMA LTD, UNIT VI, HYDERABAD, INDIA - EIRS, 843S, CO RESP 9/21/12
2013-5134	07/05/2013 08/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ASTRAZENECA, MACCLESFIELD, CHESHIRE, UK - EIRS, 483S, CO RESP 3/16/12
2013-5135	07/05/2013 08/02/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	AKORN INC, DECATUR, IL - EIRS, 483S, CO RESP 10/26/11
2013-5136	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Cliff Katz KELLEY DRYE & WARREN LLP	CELECOBIX - DATE OF FIRST SUBSTANTIALLY COMPLETE GENERIC DRUG APPLICATION
2013-5137	07/08/2013	FDA/OMPT/CBER/OCOD/DDOM/	Christine Livoti	COMPLETE RESPONSE LETTERS - TOTAL NUMBER

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	08/05/2013	ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BIOPHARM INSIGHT	ISSUED PER YEAR FOR NDA, BLA (01/01/2008 - 12/31/2012)
2013-5138	07/08/2013 08/05/2013	ORA/ORM/ ORA/ORM/ FDA/OC/OES/DFOI/ ORA/OE/ ORA/OE/	Querida Anderson BIOPHARM INSIGHT	BIOPHARM, GENERIC, PHARMACEUTICALS ETC - LIST OF INSPECTIONS (04/01/2013 - 06/30/2013)
2013-5139	07/08/2013 08/05/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOIA REQUESTS CLOSED 06/01/13 TO 6/30/13
2013-5140	07/08/2013 08/05/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	FOI DAILY LOG 6/1-30/2013
2013-5141	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	FDA INVESTIGATING REPORTS OF POSSIBLE INCREASED RISK OF PANCREATITIS ETC - RESEARCH PROVIDED TO FDA; ANALYSES OF AERS; FDA SAFETY STUDIES ETC
2013-5142	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Fuson American Association for Justice	ESSURE - ADVERSE EVENT REPORTS
2013-5143	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Carney Forsyth Medical Center	ZOLEDRONIC ACID, IBANDRONATE SODIUM - AERS
2013-5144	07/08/2013 08/05/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robin Primeau MURRAY LAW FIRM	ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE RECS
2013-5145	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eva von Schaper BLOOMBERG NEWS	RANBAXY LABORATORIES. MOHALI, INDIA - INSPECTION RECS

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2013-5146	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul E. Greenberg Analysis Group, Inc.	FDA SURVEILLANCE OF ADVERSE DRUG EFFECTS - ALL RECS
2013-5147	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ziad Gellad, MD MPH Gellad, Ziad	MIRENA IUD - AERS
2013-5148	07/08/2013 08/05/2013	FDA/OF/CFSAN/OCD/EOS/	John Lauerman BLOOMBERG NEWS	TA-65 - AERS
2013-5149	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Linda Kariya Nihon Kohden Corporation	K964122
2013-5150	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeffery A. Pecoraro Home	COMPLAINT 130596 - RECS RE CDRH FOLLOW UP
2013-5151	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shin Kang WELLS FARGO	TECFIDERA, KALYDECO, STRIBILD - AERS
2013-5152	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	William Slevin Post Medical	K072667
2013-5153	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ken Greenberg Ghost Tree Capital	JUXTAPID, LOMITAPIDE, KYNAMRO, ETC - AERS
2013-5154	07/08/2013 08/05/2013	FDA/OF/CFSAN/OCD/EOS/	joseph pereira emerson college	DIETARY SUPPLEMENTS - HOSPITAL EMERGENCY ROOM ADMISSIONS AND DEATHS IN NEW ENGLAND
2013-5155	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Quinlan Power Rogers & Smith, P.C.	DESMOPRESSIN - AERS
2013-5156	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Susan Todd West-Ward Pharmaceutical Corp.	CIPLA, LTD, MUMBAI, INDIA - 483

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2013-5157	07/08/2013 08/05/2013	FDA/OMPT/CTP/OD/	Mark Greenwold Campaign for Tobacco Free Kids	ALL RECS RE RISK ASSESSMENT MODEL USED BY FDA IN EVALUATING THE TOXICITY OF PRODUCTS UNDER THE TECHNICAL PROJECT LEAD MEMORANDA RE SE REPORTS SE0003730 SE0003731
2013-5158	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Post Medical Post Medical	K111085
2013-5159	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nalini Singh University of Kansas, School of Pharmacy	ANDA 040479
2013-5160	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rishi Sinha Stryker Inc.	K122160
2013-5161	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	James Peluso Avid Radiopharmaceuticals, Inc.	DR COLEMAN, DUKE UNIVERSITY PET FACILITY - EIR (11/01/2010 - 11/30/2010)
2013-5162	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Sakai Adamas Pharmaceuticals	NDA 19385
2013-5163	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sharon Sakai Adamas Pharmaceuticals	NDA 19334
2013-5164	07/08/2013 08/05/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mathieu CHARVERIAT THERANEXUS	PREGABALIN (LYRICA), DULOXETIN (CYMBALTA), AMITRIPTYLIN (as LAROXYL) ETC - SAFETY LABELING CHANGES, SBA, ADVISORY COMMITTEE MINUTES ETC
2013-5165	07/08/2013 08/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Dr. Rudy Zimmer Dr. Rudy Zimmer	DUKORAL - BLA
2013-5166	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD Pharmaceuticals, Inc.	ICLUSIG - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5167	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Scott Carlson AVON PRODUCTS, INC.	OHIO ALUMINUM CHEMICALS, LLC, HAMILTON, OH - 483, EIR (01/01/2009 - 07/05/2013)
2013-5168	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Nicole Norfleet STAR TRIBUNE	HMONGTOWN MARKETPLACE, HMONG VILLAGE, ST PAUL, MN - COMPLAINTS
2013-5169	07/08/2013 08/05/2013	FDA/OF/CFSAN/OCD/EOS/	Jim Huang Bemis Company, Inc.	THRESHOLD OF REGULATION RECORD 08-001 RE USE OF POLYURETHANE ADHESIV E IN FOOD PACKAGING FOR MICROWAVE COOKING
2013-5170	07/08/2013 08/05/2013	FDA/OF/CFSAN/OCD/EOS/	Amy Stewart Amy Stewart	ANGOSTURA BARK, EXTRACT ON GRAS LIST
2013-5171	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Conkling, Practice Manager Meadowlark Family Healthcare	PRAMIPEXOLE - STUDIES
2013-5172	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Conkling Meadowlark Family Healthcare	PRAMIPAXOLE DIHYDROCHLORIDE FOR DEPRESSION - STUDIES
2013-5173	07/08/2013 08/05/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/	Rachel Johnson FOI Services, Inc.	TOBACCO FILLER MATERIAL
2013-5174	07/08/2013 08/05/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SUBSTANTIAL EQUIVALENCE
2013-5175	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	JUXTAPID (LOMITAPIDE) - AERS
2013-5176	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	MERCK CONSUMER CARE - OXYTROL (OXYBUTYNIN) NDA 202-211 LBLG

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2013-5177	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	FAREVA RICHMOND, INC; PHARMACEUTICS INTRNTIONAL; UNITED THERAPEUTICS CORP - 483S 5/1-31/13
2013-5178	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	FOREST PHARMACEUTICALS INC, CINCINNATI, OH - EIR, 483, CO RESP 11/5/12
2013-5179	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	AKOM INC; AVA INC; RICHARD WOLF MEDICAL INSTRUMENTS CORP, ETC - 483S 5/1-31/13
2013-5180	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	GADAL LABORATORIES INC, MIAMI, FL - EIR, 483, CO RESP 1/23/13
2013-5181	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/ FDA/OC/OES/DFOI/	ROBERT KING FDA NEWS	PETNET SOLUTIONS INC; SCM TRUE AIR TECHNOLOGIES LLC; TRANSDERMAL CAP INC, ETC - 483S 5/1-31/13
2013-5182	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAEB CENTER FOR HEALTH RESEARCH IRB, TAMPA, FL - EIR, 483, CO RESP 1/30/13
2013-5183	07/08/2013 08/05/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	ORIGINAL CREAM CO; KALCHEM INTERNATIONAL INC; TULSA DENTAL PRODUCTS LLC (TULSUA DENTAL SPECIALTIES), ETC - 483S 5/1-31/13
2013-5184	07/08/2013 08/05/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	NEW VISTAS INC; TMJ MEDICAL LLC, SUMMIT MEDICAL PRODUCTS INC, ETC - 483S 5/1-31/13
2013-5185	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	LIFESOUTH COMMUNITY BLOOD CENTERS, CHIEFLAND, FL - EIR, 483, CO RESP 1/31/13
2013-5186	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	BAXTER PHARMACEUTICAL SOLUTIONS INC; CRACO PHARMACEUTICAL LABORATORIES LTD; FLOTEC INC - 483S 5/1-31/13
2013-5187	07/08/2013 08/05/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MSD INTERNATIONAL GMBH PUERTO RICO BRANCH LLC, ARECIBO, PR - EIR, 483, CO RESP 1/24/13
2013-5188	07/08/2013 08/05/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	ARCH PHARMALABS LTD; ESTEVE QUIMICA S A; SHILPA MEDICARE LTD, ETC - 483S 5/1-31/13
2013-5189	07/08/2013 08/05/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	NOVUM PHARMACEUTICAL RESEARCH SERVICES, PITTSBURGH, PA - EIR, 483, CO RESP 2/19/13
2013-5190	07/08/2013 08/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	ULRICH GMBH & CO KG; CSR ELETRONICA; ITALIA MEDICA SRL, ETC - 483S 5/1-31/13

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2013-5191	07/08/2013 08/05/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	ERGOSAFE PRODUCTS LLC; SUNBEAM PRODUCTS INC; BAYER HEALTH CARE LLC - 483S 5/1-31/13
2013-5192	07/08/2013 08/05/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	MICHAEL E PICHICHERO MD, ROCHESTER, NY - EIR, 483, CO RESP 6/29/12
2013-5193	07/08/2013 08/05/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	HAEMONETICS CORP; JENSEN INDUSTRIES INC; HUESTIS MACHINE CORP, ETC - 483S 5/1-31/13
2013-5194	07/08/2013 08/05/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO - EIR, 483,CO RESP 1/25/13
2013-5195	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	LAXMI DENTAL LAB USA INC; VITAIRE CORP; ALMARK TOOL & MANUFACTURING COMPANY INC, ETC - 483S 5/1-31/13
2013-5196	07/08/2013 08/05/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALFRED J RODRIGUEZ MD, PA, PLANO, TX - EIR, 483, CO RESP 2/7/13
2013-5197	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	BIOMEDICAL RESEARCH FOUNDATION OF NORTHWEST LOUISIANA; TOTAL PHARMACY SERVICES INC; QUALITEST PHARMS - 483S 5/1-31/13
2013-5198	07/08/2013 08/05/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	CENTRAL RADIOPHARMACEUTICAL SERVICES INC; NORTH SHORE LIJ/RESEARCH INSTITUTE; A & Z PHARMACEUTICALS INC, ETC - 483S 5/1-31/13
2013-5199	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	NORTHTEC LLC; HOME INFUSION SYSTEMS INC; DT DAVIS ENTERPRISES LTD, ETC - 483S 5/1-31/13
2013-5200	07/08/2013 08/05/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	NOVARTIS VACCINE & DIAGNOSTICS INC; BAYER HEALTHCARE PHARMACEUTICALS INC; INTELAMETRIX INC, ETC - 483S 5/1-31/13
2013-5201	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	ST JUDE MEDICAL PUETRO RICO LLC; BECTON DICKINSON CARIBE LTD; ZIMMER MANUFACTURING BV - 483S 5/1-13/13
2013-5202	07/08/2013 08/05/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	BIOTRONICK INC; PARKS MEDICAL ELECTRONICS INC; JUBLIANT HOLLISTERSTIER, LLC, ETC - 483S 5/1-31/13
2013-5203	07/08/2013 08/05/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	AMOCOR FLEXIBLES COMMERCE; DISCUS DENTAL LLCL; UNICARE BIOMEDICAL INC, ETC - 483S 5/1-13/13
2013-5204	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	SHELLY D SENDERS MD, SOUTH EUCLID, OH - EIR, 483, CO RESP 7/17/12
2013-5205	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	CORERX INC; HOIZON PHARMACEUTICALS INC; ATLANTIC PRO NUTRIENWTS INC (XYMOGEN), ETC 483S 5/1-31/13
2013-5206	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	UPSHER SMITH LABORATORIES INC, MAPLE GROVE, MN - EIR, 483, CO RESP 3/1/13

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2013-5207	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, JAYUYA, PR - EIR, 483, CO RESP 3/13/13-4/19/13
2013-5208	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BAXTER HEALTHCARE CORP, MARION, NC - EIR, 483, CO RESP 11/7-16/12
2013-5209	07/08/2013 08/05/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BOSTON SPINE GROUP, NEWTON, MA - EIR, 483, CO RESP 11/15/11-12/7/11
2013-5210	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CONTRACT PHARMACEUTICAL SERVICES OF AUSTRALIA PTY LTD, NORTH RYDE, NSW, AUSTRALIA - EIR, 483, CO RESP 10/30/12-11/1/12
2013-5211	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPIRA, LAKE FOREST, IL - EIR, 483, CO RESP 10/3-10/12
2013-5212	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS INTERNATIONAL AG, BASEL, SWITZERLAND - EIR, 483, CO RESP 10/15-23/12
2013-5213	07/08/2013 08/05/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NOVARTIS CONSUMER HEALTH, LINCOLN, NE - EIR, 483, CO RESP 6/13/11-7/8/11
2013-5214	07/08/2013 08/05/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AGROPHARMA LABORATORIES INC, SALINAS, PR - EIR, 483, CO RESP 3/20/13
2013-5215	07/08/2013 08/05/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AERO COMPRESSED GASES INC, MILWAUKEE, WI - EIR, 483, CO RESP 2/5/13
2013-5216	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	RPG LIFE SCIENCES LTD 463, MUMBAI, MAHARASHTRA, INDIA - EIR, 483, CO RESP 11/20-24/12
2013-5217	07/08/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	KEDRION SPA, BOLOGNANA, ITALIA - EIR, 483, CO RESP 4/18/12

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2013-5218	07/08/2013 08/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ACE JAPAN CO LTD, HIGASHINE, JAPAN - EIR, 483, CO RESP 10/26/12
2013-5219	07/08/2013 08/05/2013	FDA/OC/OES/DDM/	PETER S. HARRIS PREMIER DUE DILIGENCE	DKT & DKT LOG OF 1995N-0259
2013-5220	07/09/2013 08/06/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	ROBERT KING FDA NEWS	CARDIOGENESIS CORP - 483S 5/1-31/13
2013-5221	07/09/2013 08/06/2013	FDA/OF/CFSAN/OCD/EOS/	CHRISTINE FORGUES MORGAN LEWIS & BOCKIUS LLP	ROCK STAR ENERGY DRINK - CAERS 10/12 TO PRESENT
2013-5222	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	CHASTINE 12B2563, JAMES	IPRATROPIUM, EICOSAPENTAENOIC, BECHOMETHASOME, ETC - RECS
2013-5223	07/09/2013 08/06/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	PATRICIA L REGENYE Celgene Corporation	EVAN HERSH, ARIZONA CANCER CTR, TUCSON, AZ - 483S 6/00 TO PRESENT
2013-5224	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN RPH MS SCD INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 6/1- 30/13
2013-5225	07/09/2013 08/06/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	MARISOL FERNANDEZ GRIFOLS BIOLOGICALS INC	BAXTER HEALTHCARE CORP, MARION, NC - EIRS, 483S 1/12 TO 5/13
2013-5226	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	DONALD HENTON COVIDIEN	2012-200 - DELETED RECS
2013-5227	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	AMY MITCHELL GLAXO SMITH KLINE	GLAXOSMITHKLINE, PARMA - QUALITY ASSURANCE PROFILE (QAP)
2013-5228	07/09/2013 08/06/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CATHERINE GILFEDDER REPRIEVE	ANIP ACQUISITION CO - WARNING LTR, CO RESP, REGLAN CORR 9/11 TO PRESENT, ETC

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/		
2013-5229	07/09/2013 08/06/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	CATHERINE GILFEDDER REPRIEVE	BIOSANTE PHARMACEUTICALS INC - VIOLATIONS, INVESTIGATIONS
2013-5230	07/09/2013 08/06/2013	FDA/OMPT/OSMP/OOPD/	STANLEY SATZ PHD Advanced Imaging Projects, Inc.	LEUCOVORIN - STABILITY DATA, APRVL LTR, CORR, ETC
2013-5231	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	CODY MONROE ASE Direct Inc.	FDA GOVERNMENT PURCHASE CARD HOLDERS NAMES AND PHONE NUMBERS LAST 2 YRS
2013-5232	07/09/2013 08/06/2013	FDA/OO/OFBA/OAGS/	ALEXANDER CAMPBELL 32BJ SEIU	BUDGET SERVICES & SUPPLIES LLC - CONTRACT #HHSF223201310006C
2013-5233	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	ZOLEDRONIC - AERS
2013-5234	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Doe J	TAKEDA LABS - SOLUTAB PHARMACOLOGY RECS, EIRS 1/06 TO PRESENT
2013-5235	07/09/2013 08/06/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-5236	07/09/2013 08/06/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	COCA COLA CO, PEPSI CO - USE OF 4-METHYLIMIDAZOLE CORR 2009 TO PRESENT
2013-5237	07/09/2013 08/06/2013	FDA/OF/CFSAN/OCD/EOS/	TOM NASH MUCKROCK NEWS	USE OF 4-METHYLIMIDAZOLE IN SODA - RPTS, MEMOS 2009 TO PRESENT
2013-5238	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL ZIMKOWSKI UNIV OF COLORADO AT DENVER	PARIETEX MONOFILAMENT POLYESTER MESH K090858
2013-5239	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL ZIMKOWSKI UNIV OF COLORADO AT DENVER	COMPOSIX L/P MESH WITH ECHO PS POSITIONING SYS K102788
2013-5240	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHANIE PHILBIN GOODWIN PROCTER LLP	ACRYSOF UV ABSORBING INTRAOCULAR LENSES P930014, META-MV PACING SYS P880038 - SS&E

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2013-5241	07/09/2013 08/06/2013	FDA/OC/OES/DDM/	ROBERT F CHURCH HOGAN LOVELLS US LLP	DKT 1975N-0336
2013-5242	07/09/2013 08/06/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	MICHAEL MASUDA NOLAND HAMERLY ETIENNE & HOSS	ROBERT A HOHBERG, HOHBERG POULTRY RANCHES, ONTARIO, CA; FONTANA, CA - APRVLS, INVESTIGATIONS, VIOLATIONS, ETC 1994 TO PRESENT
2013-5243	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	FRULLO JR, RAYMOND L	ARM & HAMMER TOOTHPASTE - INSP RESULTS LAST TEN YRS
2013-5244	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	MERZ PHARMS - NAFTIN (NAFTIFINE HCL) NDA 204-286 SBA, MOR, LBLG, ETC
2013-5245	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom PFIZER	XOLAIR - SBA
2013-5246	07/09/2013 08/06/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OF/CFSAN/OCDEOS/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-5247	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 020336 - SBA
2013-5248	07/09/2013 08/06/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-5249	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 07/01/2013 - 07/05/2013
2013-5250	07/09/2013 08/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NINGBO SMART PHARMACEUTICAL COMPANY, CHINA - INVESTIGATOR DIARY
2013-5251	07/09/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DEBORAH M FIELD	INDIVIDUAL RECS

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	08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	MORRIS & MORRIS	
2013-5252	07/09/2013 08/27/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Rachel Johnson FOI Services, Inc.	BK120067
2013-5253	07/09/2013 08/06/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MATTHEW T JONES MCFARLANE & DOLAN LAW OFCS	ST JUDE MEDICAL - EON MINI-3788 (PG) RECALL RECS
2013-5254	07/09/2013 08/06/2013	FDA/OC/OES/DDM/	Mark Oremus MCMASTER UNIVERSITY	PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS ADVISORY COMMITTEE - RECS RE 7/7/89 MTG
2013-5255	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Bob Ciesla Personal Consumer Information	ISR 6555078 6647694 6867721 ETC
2013-5256	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tim Lohnes Orchid Design	K092309
2013-5257	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachelle Lyon JANUS CAPITAL GROUP INC	ZYTIGA, XTANDI - AERS
2013-5258	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	Carol L. Price Carol L. Price	DAVINCI ROBOTIC SURGICAL DEVICE - RECS RE DEFECT
2013-5259	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	K973806
2013-5260	07/09/2013 08/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran & Associates	K926508
2013-5261	07/09/2013 08/06/2013	FDA/OO/OFBA/OAGS/	Marcy Welkie MPF Federal, LLC	HHSF223200830014I
2013-5262	07/09/2013 08/06/2013	FDA/OF/CFSAN/OCD/EOS/	Dojin Ryu University of Idaho	OCCURENCE OF OCHRATOXIN IN FOODS AND AGRICULTURAL COMMODITIES
2013-5263	07/09/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Nicole Norfleet	HMONGTOWN MARKETPLACE, HMONG VILLAGE, ST PAUL, MN - COMPLAINTS

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	08/06/2013		STAR TRIBUNE	
2013-5264	07/09/2013 08/06/2013	FDA/OC/OES/DFOI/	Yingchao Xiao Lee & Xiao	IMPORTER, EXORTER
2013-5265	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	b.burgess BURGESS, BERNIE	CONVERSATION BY DAN-MY CHU DS1 1/24/07 RE C1639
2013-5266	07/09/2013 08/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Christopher J. Gansen Gansen Law Group, P.C.	HEMOFIL M - AERS
2013-5267	07/09/2013 08/06/2013	FDA/OO/OFBA/OAGS/	Tyson Bellamy FEFA LLC	HHSF223201210142C
2013-5268	07/10/2013 08/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT O DEAN COMPLIANCE SYSTEMS INTERNATIONAL LLC	GRI MEDICAL & ELECTRONIC TECHNOLOG CO LTD, JIAXING, ZHEJIANG, CHINA - EIRS, 483S, ACTION PLAN MOST CURRENT
2013-5269	07/10/2013 08/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	MARA CALER ALERE DAN DIEGO INC	BECKMAN COULTER INC - ACCESS TNL TEST K121214
2013-5270	07/10/2013 08/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	REID BECK BECK & AMSDEN PLLC	ABILIFY - AERS
2013-5271	07/10/2013 08/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OC/OES/DFOI/	HATTON 1519223, ROLAND	MIRAPOX - ISRS 4100477, 4124388, 5856767, ETC
2013-5272	07/10/2013 08/07/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	LESLIE LOCHMAN CAPE RADIOLOGY GROUP	MERCERVILLE RADIOLOGY ASSOCIATES PA - WARNING LTR CLOSE OUT LTR 5/19/97
2013-5273	07/10/2013 08/07/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OC/OES/DFOI/	VINCENT TONG BURESH KAPLAN FELLER AT EL	MMI, CUPERTINO, CA - EIR, ATTACHMENTS, EXHIBITS 4/16/12-5/8/12

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		FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/		
2013-5274	07/10/2013 08/07/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N BLUE ZETETIC INC	FIBREBOARD BOXES STE HAIR CARE PRODS ENTRY NUMBER EHP-007191-6 (SHAMPOO, CONDITIONER) - PHOTOGRAPHS, OASIS SCREEN SHOTS
2013-5275	07/10/2013 08/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISR 3170570, 3567433, 3764906, ETC
2013-5276	07/10/2013 08/07/2013	FDA/OO/OHR/	PAUL VACLAVIK	PER CORE V USPS HHS-FDA-MP-11-463297, HHS-CDRH-DE-11-511106, HHS FDA-MP-11-493192, ETC APPLICANT QUALIFICATIONS
2013-5277	07/10/2013 08/07/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	SAMANWTHA MYERS ROANOKE CLAIMS SERVICES	ENTRY NUMBER DC101014389 - LIST FDA NOTICE OF ACTION, BILLS OF LANDING COMMERCIAL INVOICES, ETC
2013-5278	07/10/2013 08/07/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	PATRICK J CAULFIELD GRUNFELD DESIDERIO LEBOWITZ ET AL	OLEIFICIO MONTALBANO SPA (MONTALBANO AGRICOLA ALIMENTARE TOSCANA SPA); COSTA D'ORO SPA - OLIVE OIL NONEXEMPT RECS
2013-5279	07/11/2013 08/08/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	JOHN P KROMER CONNORS & VILARDO LLP	LEWISTON COMMERICAL WAREHOUSE - LEGIONNAIRES DISEASE INVESTIGATION RECS, TEST RESULTS, EMAILS, ETC
2013-5280	07/11/2013 08/08/2013	FDA/OC/OES/DFOI/	CHRISTINA RAFFAELE AVALON RISK MANAGEMENT INC	ENTRY #60510811122 - NOTICE OF FDA ACTION #1
2013-5281	07/11/2013 08/08/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	CYNTHIA L MAZZUTO RN LYTAL REITER CLARK ET AL	INDIVIDUAL RECS
2013-5282	07/11/2013 08/08/2013	FDA/OC/OES/ FDA/OGROP/OIP/	DAVID G MORGAN REUTERS	PLANNED EXPANSION OF FDA INSP CAPACITY IN CHINA
2013-5283	07/11/2013 08/08/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/ORP/DIDP/	CONNOR G SHEEHAN DUNN SHEEHAN LLP	GLAXOSMITHKLINE LLC - LAMICTAL AERS, CLNCL TRIALS, RISK ASSESSMENTS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/		
2013-5284	07/11/2013 08/08/2013	ORA/ ORA/ ORA/ORM/ ORA/ORM/ ORA/OE/ ORA/OE/	ERICA JORGENSEN WSB-TV Special Projects	INSPS IN GEORGIA 7/1/08 TO 7/1/13
2013-5285	07/11/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/ORO/DIOP/ OC/OCC/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	JON M SANDS FEDERAL PUBLIC DEFENDER ARIZONA	SODIUM THIOPENTAL, PENTOBARBITAL SODIUM, PROPOFOL, ETC - IMPORTATION RECS 2/1/11 TO PRESENT

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		FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/		
2013-5286	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOSEPH KICEINA ABBOTT POINT OF CARE INC	HEMOCHRON JR APTT K940401, K923761; HEMOCHRON JR GENERATION II K974799, ETC
2013-5287	07/11/2013 08/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RYE, SHANIAN	MEDICATIONS APPROVED TO TREAT MENTAL ILLNEESES IN ILLINOIS
2013-5288	07/11/2013 08/08/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	THANKUR, CHANDAR	CR BARD INC - WARNING LTR SJN-08-06 7/22/08, #03-ATL-26 9/16/03 CLOSEOUT RECS
2013-5289	07/11/2013 08/08/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	THANKUR, CHANDAR	LIFECCELL CORP - WARNING LTR #09-NWJ-01 10/1008, 5/5/011
2013-5290	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	DMI BLOOD GAS ANALYZER & CARTRIDGE K924758
2013-5291	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA SL BLOOD ANALYSIS SYS CR CARTRIDGE K030035
2013-5292	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS LACTATE CARTRIDGE K013938
2013-5293	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA SL BLOOD ANALYSIS SYS GL CARTRIDGE K011586
2013-5294	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS K981270

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2013-5295	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS WITH OPTIONAL MULTI-USE CARTRIDGE K980523
2013-5296	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS K974396
2013-5297	07/11/2013 08/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	IRMA BLOOD ANALYSIS SYS K945240
2013-5298	07/12/2013 08/09/2013	FDA/OC/OES/DFOI/	Carol L. Price Carol L. Price	DAVINCI ROBOTIC SURGICAL DEVICE - REPORTS OF PROBLEMS
2013-5299	07/12/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	C. Gansen GANSEN LAW GROUP	HEMOFIL - AERS
2013-5300	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NINGBO SMART, NINGBO, CHINA - EIR, 483, CORR
2013-5301	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	George Martens Carbunny LLC	BIOLOGICAL DEVIATION REPORTS SUBMITTED BY OHIO STATE UNIVERSITY MEDICAL CENTER
2013-5302	07/12/2013 08/09/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Melissa McCaughey DePuy Synthes Spine	DEPUY MITEK, DEPUY ORTHO - EIR 08/03/2012 - 07/01/2013
2013-5303	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Franolic VersaPharm Inc.	ANDA 202459 - SBA
2013-5304	07/12/2013 08/09/2013	FDA/OF/CFSAN/OCD/EOS/	Todd McInerney Magrabar Chemical Corporation	ENZYME TECHNICAL ASSOCIATION - SUBMISSIONS ON ANTIFOAMS AND FLOCCULANTS
2013-5305	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Daniel Lin ELI LILLY & CO	NDA 018450) filed by Abbvie in September 1981
2013-5306	07/12/2013 08/09/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	David Luke Palmer Natural Products	PALMER NATURAL PRODUCTS - TRANSCRIPT OF CALL WITH SEATTLE DISTRICT 06/18/2013
2013-5307	07/12/2013 08/09/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Rachel Johnson FOI Services, Inc.	APPLIED NUTRITION CORPORATION - EIR, 483, CORR ETC

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2013-5308	07/12/2013 08/09/2013	FDA/OMPT/CTP/OD/	Desmond Jenson Tobacco Control Legal Consortium	GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION - CORR, SUMMARIES, ETC (06/22/2009 - 07/09/2013)
2013-5309	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa Experien Group LLC	K961385 - TRANSFER OF OWNERSHIP LETTER
2013-5310	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Bao Tran Tran Associates	K983658, K090169, K090598 ETC
2013-5311	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Sergey Zavvalov, Sergey	K980745, K033448
2013-5312	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	James Heaney Heaney, James	REGISTERED ACTIVE INGREDIENT PRODUCERS FOR CAS# 8001-54-5; FEGISTERED INNERT INGREDIENT PRODUCERS FOR CAS# 8001-54-5
2013-5313	07/12/2013 08/09/2013	FDA/OC/OES/DFOI/	Liz Szabo USA TODAY	PREVIOUSLY FILED FOIA
2013-5314	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K930836
2013-5315	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K910483
2013-5316	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Michael Garff Fresh Medical Laboratories	K032350, K874181
2013-5317	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cora Sim Ellipse Technologies, Inc.	K031875
2013-5318	07/12/2013 08/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	LINEZOLID - SBA
2013-5319	07/12/2013 08/09/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Matthew J Dodds CITIGROUP	ST JUDE SYLMAR, CA FACILITY - ALL RECS (03/01/2013 - 07/11/2013)
2013-5320	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 3018238-7, 3118880-9, 3019234-6, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5321	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	ANOKI J KAPASI DEGGE GROUP LTD	ISRS - 4828879-X, 4711307-2, 4616001-4, ETC
2013-5322	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 321823-0, 3143443-9, 3158856-9, ETC
2013-5323	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Xin Pan Weiss Asset Management	STRIDES ARCOLAB - 483 (06/01/2013 - 07/10/2013)
2013-5324	07/12/2013 08/09/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Eric White MISSION PHARMACAL COMPANY/PRESIDENT	PURETEK CORPORATION, SAN FERNANDO, CA - 483 (07/01/2010 - 07/31/2013)
2013-5325	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Strickler CBS NEWS	RANBAXY FOREIGN FACILITIES - INSPECTION RECS, NOTES, 483 ETC (01/01/2011 - 01/01/2013)
2013-5326	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas M. Burton THE WALL STREET JOURNAL	CLINICAL INSPECTION SUMMARY BY OFFICE OF SCIENTIFIC INVESTIGATIONS RE CLINICAL TRIALS
2013-5327	07/12/2013 08/09/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/	Ricky Swan Swan, Ricky L	SWAN BROS DAIRY INC, CLAREMORE, OK - EIR, LAB REPORTS
2013-5328	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 3594674-5, 3911077-1, 3977207-0, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-5329	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANOKI J KAPASI DEGGE GROUP LTD	ISRS - 438568-8, 4584792-7, 4389882-X, ETC
2013-5330	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 6135920-3, 5317709-8, 5317711-6, ETC
2013-5331	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeannie Lin Route One Investment Company	AGILA SPECIALTIES - 483 (06/17/2013 - 07/10/2013)
2013-5332	07/12/2013 08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANOKHI J KAPASI DEGGE GROUP LTD	ISRS - 6905200-4, 7033816-6, 7777191-8, ETC
2013-5333	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAULL CAMPBELL VASCULAR SOLUTIONS INC	VASCULAR SOLUTIONS INC, ZERUSA LTD - GUARDIAN HEMOSTATIS VALVE K052381, K073620
2013-5334	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAM PUMMILL SYBRON DENTAL SPECIALTIES	SONENDO INC, LAGUNA HILLS, CA - ENDOTHERAPY SYS K130025
2013-5335	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	NAYAN RAVAL SILARX PHARMACEUTICALS INC	SILARX PHARMACEUTICALS INC, SPRING VALLEY, NY - QAP
2013-5336	07/12/2013	FDA/OMPT/CDER/GRP/DIDP/		ISRS 3477397, 4103405, 4139030, ETC

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	08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMO, SALIH	
2013-5337	07/12/2013 08/09/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	STEVEN E FORMAKER FREEDMAN & TAITELMAN LLP	WISDOM PROTEINS INC, SAN DIEGO, CA - CMLPTS, INVESTIGATION, CONSENT AGREEMENTS 1/11 TO PRESENT
2013-5338	07/12/2013 08/09/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OC/OES/DFOI/	TAYLOR, DOREEN A	COMPLIANCE RPT 130314
2013-5339	07/12/2013 08/09/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Robert Pyrtle Pyrtle, Robert	SCANTIBODIES BIOLOGICS, INC, EL CAJON, CA - EIR (01/01/2013 - 07/10/2013)
2013-5340	07/12/2013 08/09/2013		PETER HARRIS PREMIER DUE DILIGENCE	DKT 1995N-0259
2013-5341	07/12/2013 08/09/2013		HILLARY RUBIN KENYON & KENYON LLP	DKT 1995S-0316
2013-5342	07/12/2013 08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher Smith Symmetry Medical Inc.	K012105
2013-5343	07/12/2013 08/09/2013	FDA/OF/CFSAN/OCDE/EOS/	Anahad OConnor NEW YORK TIMES	MEAL REPLACEMENT PRODUCTS - AERS
2013-5344	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	A1481259 STUDY TO ASSESS PDE5
2013-5345	07/12/2013 08/09/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OFO/OFM/BTAMS /	Michael Felberbaum THE ASSOCIATED PRESS	CTP - BUDGETS, USER FEES
2013-5346	07/12/2013 08/14/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Diane Lehman wilson UNIVERSITY OF MICHIGAN MEDICAL SCHOOL	UNIVERSITY OF MICHIGAN - EIR 02/10/2010 - 02/10/2012
2013-5347	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dheeresh Pathak Dheeresh Pathak	AGILA SPECIALTIES - 483 (01/01/2013 - 07/10/2013)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5348	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Lin BIOLOGICS CONSULTING GROUP	SKYLA - APPROVAL RECS
2013-5349	07/12/2013 08/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neal Wadhwa Partner Fund Management	STRIDES ARCOLAB - 483 06/15/2013 - 07/10/2013
2013-5350	07/12/2013 08/09/2013	FDA/OC/OES/DFOI/	Michael Felberbaum THE ASSOCIATED PRESS	CTP FOIA REQUESTS
2013-5351	07/15/2013 08/12/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Mariela Ochoa Swiss Caps, USA, Inc.	SWISS CAPS USA - EIR REDACTED 11/08/2010 TO 11/17/2010
2013-5352	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kristen Bunnell, PharmD RHODE ISLAND HOSPITAL	LEVETIRACETAM - AERS
2013-5353	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chris Hutts Cantrell Drug Company	OUTSOURCE HUMAN DRUG COMPOUNDER BUSINESS CLASSIFICATION
2013-5354	07/15/2013 08/12/2013	FDA/OF/CFSAN/OC/DOS/	ryan houser Vemma	VERVE - CAERS
2013-5355	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	joe enos enos, joe	LORAZAPM - AERS, VIOLATIONS
2013-5356	07/15/2013 08/12/2013	CVM/OC/D/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	NADA 141-345
2013-5357	07/15/2013 08/12/2013	ORA/ ORA/ FDA/OC/OES/DFOI/	Denise Malan Investigative Reporters and Editors	OASIS DATA

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		FDA/OGROP/ORO/ORO/DIOP/		
2013-5358	07/15/2013	FDA/OMPT/CDER/GRP/DIDP/	A. Luke Smith	ANDA 077571 ROUTING SHEET
	08/12/2013	FDA/OMPT/CDER/GRP/DIDP/	FARUQI & FARUQI LLP	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-5359	07/15/2013	FDA/OMPT/CBER/OCOD/DDOM/	Barry Gene Hicks	BK120067
	08/21/2013	ALFB/	Fresenius-Kabi USA	
2013-5360	07/15/2013	FDA/OMPT/CDER/GRP/DIDP/	A. Luke Smith	ANDA 077571 FINAL APPROVAL LETTER
	08/12/2013	FDA/OMPT/CDER/GRP/DIDP/	FARUQI & FARUQI LLP	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-5361	07/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton	A copy of the releasable inspection report from November 2012 for: Boehringer-Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany
	08/12/2013	FDA/OMPT/CDER/GRP/DIDP/	INC RESEARCH CONSULTING &	
		FDA/OMPT/CDER/GRP/DIDP/	SUBMISSIONS	
		FDA/OMPT/CDER/GRP/DIDP/		
2013-5362	07/15/2013	FDA/OC/OES/DFOI/	Irene Libin	DA VINCI SURGICAL SYSTEM
	08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steven H. Schafer & Associates	
2013-5363	07/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Cathy Burgess	STRIDES ARCOLAB - 483 (06/01/2013 - 07/12/2013)
	08/12/2013	FDA/OMPT/CDER/GRP/DIDP/	ALSTON & BIRD LLP	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-5364	07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Carl Jenkins	K820673 K833261 K881422
	08/12/2013		WOOD BURDITT GROUP	
2013-5365	07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Casey A. Metzger	K002348 - REVIEWER NOTES
	08/12/2013		STRYKER INSTRUMENTS	
2013-5366	07/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kelly McNamara	K110639
	08/12/2013		INTUITIVE SURGICAL	
2013-5367	07/15/2013	FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton	SCF-001 AC NDA 20231 S/046
	08/12/2013	FDA/OMPT/CDER/GRP/DIDP/	INC RESEARCH CONSULTING &	
		FDA/OMPT/CDER/GRP/DIDP/	SUBMISSIONS	
		FDA/OMPT/CDER/GRP/DIDP/		
2013-5368	07/15/2013	FDA/OMPT/CBER/OCOD/DDOM/	Donald L. Bredle, PhD	REGULATORY OVERVIEW OF HYDROXYETHYL STARCH
	08/12/2013	ALFB/	University of Wisconsin - Eau	SOLUTIONS - RECS

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			Claire	
2013-5369	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Marc Weiner, M.D. UTHSCSA	RIFAMPIN - PRECLINICAL TOXICOLOGY AND SAFETY DATA
2013-5370	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alain Jordan Aleva Neurotherapeutics SA	P840001
2013-5371	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joyce Greene Joyce Greene Research	MICRONUCLEUS FORMATION MEETING - TRANSCRIPT (07/31/2000 - 08/10/2000)
2013-5372	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Sue Feldman Community Health Alliance	ADVERSE DRUG REDACTIONS IN VIRGINIA HOSPITALS (01/01/2012 - 07/13/2013)
2013-5373	07/15/2013 08/12/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	ROBERT KING FDA NEWS	MEDI FARE DRUG & HOME HEALTH CARE, BLACKSBURG, SC; BIO MERIEUX INC, DURHAM, NC - 483 6/13
2013-5374	07/15/2013 08/12/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	ROBERT KING FDA NEWS	ZIMMER TRABECULAR METAL TECHNOLOGY INC, PARSIPANNY, NJ; DELVA TOOL & MACHINE CRP, CINNAMINSON, NJ; ADVANCED PRECISION INC, SPARTA, NJ - 483 6/13
2013-5375	07/15/2013 08/12/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	ROBERT KING FDA NEWS	MAIN STREET FAMILY PHARMACY LLC, NEWBERN, TN; OWEN BIOSCIENCES INC, BATON ROUGE, LA; LEISURE PRODUCTS, INC, KINGSPORT, TN - 483 6/13
2013-5376	07/15/2013 08/12/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	ROBERT KING FDA NEWS	CARESTREAM HEALTH INC, ROCHESTER, NY; LNK INT'L INC, HAUPPAUGE, NY; AMERICARE COMPOUNDING LLC, GARDEN CITY SOUTH, NY - 483 6/13
2013-5377	07/15/2013 08/12/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	ROBERT KING FDA NEWS	TEVA PHARMACEUTICALS USA INC, SELLERSVILLE, PA; GLOBUS MEDICAL INC, AUDUBON, PA - 483 6/13
2013-5378	07/15/2013 08/12/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	ROBERT KING FDA NEWS	MOTION ANALYSIS CORP, SANTA ROSA, CA; MORGAN MEDESIGN INC, SANTA ROSA, CA; DOCXS BIOMEDICAL PRODUCTS LLC, UKIAH, CA - 483 6/13
2013-5379	07/15/2013 08/12/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	ROBERT KING FDA NEWS	AD TECH MEDICAL INSTRUMENT CORP, RACINE WI; PMT CORP, CHANHASSEN, MN; BELL INTL LABS INC, MINNEAPLOIS, MN - 483 6/13

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2013-5380	07/15/2013 08/12/2013	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	UNITED CONTACT LENS INC, ARLINGTON, WA - 483 6/13
2013-5381	07/15/2013 08/12/2013	ORA/ ORA/	ROBERT KING FDA NEWS	PT PANASONIC HEALTHCARE, INDONESIA - 483 6/13
2013-5382	07/15/2013 08/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	ROBERT KING FDA NEWS	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - 483 6/13
2013-5383	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	AFTON SCIENTIFIC LLC, CHARLOTTESVILLE, VA; PRAXIR DISTRIBUTION MID ATLANTIC LLC, JESSUP, MD - 483 6/13
2013-5384	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	7 MILE SOLUTIONS INC, MAXANT TECHNOLOGIES, NILES IL; PARO ROBOTS US INC, SCHAUMBURG, IL - 483 6/13
2013-5385	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	OHIO ALUMINUM CO, WEST CHESTER, OH; GFS CHEMICALS INC, COLUMBUS, OH - 483 6/30
2013-5386	07/15/2013 08/12/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	GENESYS ORTHOPEDIC SYS LLC, AUSTIN, TX; WILDCAT MEDICAL EQUIPMENT INC, TULSA, OK; GENESIS BIOSYSTEMS INC, LEWISVILLE, TX - 483 6/13
2013-5387	07/15/2013 08/12/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	PETNET SOLUTIONS INC, ALBUQUERQUE, NM, COLORADO MEDICAL SYCLOTRON LLC, DENVER, CO; VICON MOTION SYS INC, CENTENNIAL CO - 483 6/13
2013-5388	07/15/2013 08/12/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	SYMBIOS MEDICAL PRODUCTS LLC, INDIANAPOLIS, IN; SERVAPURE CO, BAY CITY, MI; ZIMMER INC, WARSAW, IN - 483 6/13
2013-5389	07/15/2013 08/12/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	SYSTEMS ONE LLC, STUART, FL; NOVALIS MEDICAL LLC, TAMPA, FL; TOBY ORTHOPAEDICS INC, CORAL GABLES, FL - 483 6/13
2013-5390	07/15/2013 08/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	PHARMAZEUTISCHE FABRIK, DR RECKEWEG & CO GMBH, BENSHEIM, GERMANY; SYNTRION GMBH, CAWL, GERMANY; PRODUCTS CHIMIQUES AUXILIARIES ET DE SYNTHESE SA, LIMAY, FRANCE - 483 6/13
2013-5391	07/15/2013 08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	LAERDAL MEDICAL CO LTD, SUZHOU, CHINA; CHANGZHOU DSB MEDICAL CO LTD, CHANGZHOU CITY, CHINA - 483 6/13
2013-5392	07/15/2013 08/12/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	MATHESON TRI GAS, WAVERLY, NE - 483 6/13
2013-5393	07/15/2013 08/12/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	TEVA PARENTERAL MEDICINES INC, IRVINE, CA; KC PHARMACEUTICALS INC, POMONA, CA; PRIMA PHARM INC, SAN DIEGO, CA - 483 6/13
2013-5394	07/15/2013	FDA/OGROP/ORANE-FO/NWE-	ROBERTKING	TOWER LABS LTD, CENTERBROOK, CT; BRISTOL MYERS

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	08/12/2013	DO/NWE-CB/	FDA NEWS	SQUIBB, DEVENS, MA; PRECISION DERMATOLOGY INC, CUMBERLAND, RI - 483 6/13
2013-5395	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALESHIRE 278999, DAVID .	AER - TROFRANIL ETC
2013-5396	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BENJAMIN P. LEWIS MITSUBISHI TANABE PHARMA DEVELOPMENT OF AMERICA INC	NALFURAFINE HCI - IND
2013-5397	07/15/2013 08/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	Dennis Raisch UNIVERSITY OF NEW MEXICO	MEDWATCH REPORTS
2013-5398	07/16/2013 08/13/2013	FDA/OMPT/CTP/OD/ OC/OCC/	Desmond Jenson Tobacco Control Legal Consortium	RECORDS RE LETTER FROM REYNOLDS AMERICAN SERVICES COMPANY, MANAGING COUNSEL MITCHELL NEUHAUSER TO LAWRENCE DEYTON AND ELIZABETH DICKINSON SENT 1/15/13
2013-5399	07/16/2013 08/13/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Angela Stagg IMPULSE DYNAMICS	LONESTAR, AMARILLO, TX - CORRECTION AND PREVENTATIVE ACTIONS
2013-5400	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Robin Yurk, MD, MPH Mutiple Site-National & International Multi-disciplinary	INDIVIDUAL RECS
2013-5401	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Laura Strickler CBS NEWS	WOCKHARDT - LOGS, CORR, 483 ETC (01/01/2011 - 07/01/2013)
2013-5402	07/16/2013 08/13/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Cindy Ingold, Quality Director American Red Cross Blood Services - Missouri Illinois Region	AMERICAN RED CROSS BLOOD SERVICES NORTH COUNTY CENTER, FLORISSANT, MO - EIR (12/04/2012 - 12/12/2012)
2013-5403	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	K843135
2013-5404	07/16/2013	FDA/OC/OES/DFOI/	Robert King	FOIA REQUEST LOG 7/08/2013 TO 7/12/2013

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	08/13/2013		FDANEWS	
2013-5405	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren C. Stipp Stipp, Lauren C	LIST OF EMERGENCY IND APPROVED BY FDA SINCE 2011 FOR SYNACTHEN
2013-5406	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	K931654
2013-5407	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	2013-4475
2013-5408	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	I K923260
2013-5409	07/16/2013 08/13/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	James Barton Herbalife International of America, Inc.	MANHATTAN DRUG COMPANY, HILLSIDE, NJ - EIR, WARNING LETTER (01/01/2011 - 07/15/2013)
2013-5410	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Barton Herbalife International of America, Inc.	NINGBO ZHENHAI HAIDE BIOCHEM - WARNING LETTER, EIR
2013-5411	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Joe Neel NPR National Public Radio	FOIA REQUEST LOG 01/01/2012 - 07/15/2013
2013-5412	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher T. Frenz MOUNT SINAI SCHOOL OF MEDICINE	K925565
2013-5413	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mia Ware COVIDIEN	K120657
2013-5414	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	2013-4817
2013-5415	07/16/2013 08/13/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	James Barton Herbalife International of America, Inc.	PHARMACHEM LABORATORIES, KEARNY, NJ - EIR, WARNING LETTER (01/01/2010 - 07/15/2013)
2013-5416	07/16/2013 08/13/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	James Barton Herbalife International of America, Inc.	TOWER LABORATORIES, CENTERBROOK, CT - EIR, WARNING LETTER (01/01/2010 - 07/15/2013)

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2013-5417	07/16/2013 08/13/2013	CVM/OCD/ OC/OCC/	THOMAS CLUDERAY ENVIRONMENTAL WORKING GROUP	EWG - SUPERBUGS INVADE AMERICAN SUPERMARKETS RPT CORR BTWN FDA AND REPRESENTATIVES OF THE POULTRY, LIVESTOCK OR ANIMAL FEED AND PHARMACEUTICAL INDUSTRIES
2013-5418	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	BOB O'MALLEY Segal McCambridge Singer & Mahoney	MORTON GROVE PHARMS - CARBAXEFED RECS 1/00 TO PRESENT
2013-5419	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DEENA B KLABER GIBSON DUNN & CRUTCHER LLP	GE HEALTHCARE - OMNISCAN NDA 20-123, NDA 22-066 MEMO TO FILE 5/15/07
2013-5420	07/16/2013 08/13/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ ORA/ORO/DFS/ ORA/ORO/DFS/	LOUIS KOORY ESQ MISSION LAW CENTER	SALMONELLA OUTBREAK - INVESTIGATION RECS
2013-5421	07/16/2013 09/06/2013	FDA/OMPT/CTP/OD/ FDA/OO/OFBA/OAGS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	RESEARCH TRIANGLE INSTITUTE - TOBACCO MENTHOL STUDIES HHSF223201000044C COMM, DATA ANALYSIS
2013-5422	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARK MCLEAN MEYERSON LAW FIRM PC	APP PHARMACEUTICALS LLC - HEPARIN PRODUCTION MTG MINS, CORR, TRANS, ETC
2013-5423	07/16/2013 08/13/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDRH/OCER/DFOI/	RASHIDA RICHARDSON CENTER FOR HIV LAW & POLICY	DR BERNARD BRANSON - CORR, CMLNPTS 2008 TO 2012; ORASURE TECHNOLOGIES INC - ORAQUICK RAPID HIV TESTS CORR, RECS 2008 TO 2012
2013-5424	07/16/2013	FDA/OMPT/CDER/GRP/DIDP/		CHILDREN'S TYLENOL SUSPENSION LIQUID - FAERS 1969

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	08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	TO 2013
2013-5425	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JUSTIN DIMARTINO RETROPHIN INC	NOVARTIS PHARMACEUTICAL CORP - SYNTOCINON (OXYTOCIN NASAL SOL) NDA 12-285 VOLUNTARY WITHDRAWAL 8/7/97
2013-5426	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	TUCHIN, STACEY	GC AMERICA - G-AENIAL UNIVERSAL FLO MATERIAL SAFETY DATA SHEET (MSDS)
2013-5427	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARTINEZ #1652478, ENRIQUE	UNISOM, TULENEX, PROMESCENT, ETC - RECS
2013-5428	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	PHILIPS - INTELLIVUE CLINICAL INFORMATION PORTFOLIO K100272
2013-5429	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARIANNE C LEBLANC SUGARMAN AND SUGARMAN PC	VERTEX PHARMACEUTICALS INC - INCIVEK CLNCL TRIALS, AERS, CORR, ETC
2013-5430	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAHENDER KORAPATI APPCO PHARMACEUTICALS CORP	SHIONOGI INC - ROBINUL (GLYCOPYRROLATE TABS) NDA 12-827 LBLG
2013-5431	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BILL ESPSTEIN ESQ GARMO & GARMO LLP	MAXITROL (NEOMYCIN, POLYMYXIN B, DEXAMETHASONE OPHTHALMIC SUSPENSION) - AERS
2013-5432	07/16/2013 08/13/2013	OC/OL/	Jason Cherkis The Huffington Post	FDA CORR WITH REP LOUIE GOHMERT (01/03/2005 - 07/15/2013)
2013-5433	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BILL EPSTEIN ESQ GARMO & GARMO LLP	TOBRADEX (TOBRAMYCIN AND DEXAMETHASONE OPHTHALMIC SUSPENSION) - AERS

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		FDA/OC/OES/DFOI/		
2013-5434	07/16/2013 08/13/2013	CVM/OCD/	Jeanna Wheeler Seattle Institute for Biomedical and Clinical Research	NADA 115-732
2013-5435	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martin Leitritz University Eye Hospital	XATALAN APPROVAL RECS
2013-5436	07/16/2013 08/13/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jason L. Schwartz PRINCETON UNIVERSITY	HEPTAVAX-B - DOCKET, BLA, ADVISORY COMMITTEE MEETINGS ETC
2013-5437	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eli G. Phillips, Jr. University of the Incarnate Word, Feik School of Pharmacy	PRILOSEC - ORIGINAL APPROVAL LETTER 9/14/1989
2013-5438	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eli G. Phillips Jr University of the Incarnate Word, Feik School of Pharmacy	AMOXIL - ORIGINAL APPROVAL LETTER 10/21/1980
2013-5439	07/16/2013 08/13/2013	CVM/OCD/	Kathy Hee Kathy Hee	VIVASTEM LLC, STEMPHASE - COMMUNICATIONS WITH FDA (01/01/2011 - 07/16/2013)
2013-5440	07/16/2013 08/13/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jason L. Schwartz PRINCETON UNIVERSITY	RECOMBIVAX HB - BLA, ADVISORY COMMITTEE MEETINGS
2013-5441	07/16/2013 08/13/2013	ORA/ ORA/ FDA/OC/OES/	Jason Cherkis The Huffington Post/Jason Cherkis	VA GOV BOB MCDONNELL - CORR WITHH FDA (01/01/2010 - 07/15/2013)
2013-5442	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEXANDER G PILLER LATHAM & WATKINS LLP	PADDOCK LLC - PHOSLO GELCAPS ANDA 91-312 QUALITY OVERALL SUMMARY, PHARMACEUTICAL DEVELOPMENT RPT
2013-5443	07/16/2013 08/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ALEXANDER G PILLER LATHAM & WATKINS LLP	INVAGEN PHARMACEUTICALS INC - PHOSLO GELCAPS ANDA 203-135 QUALITY OVERALL SUMMARY, PHARMACEUTICAL DEVELOPMENT RPT

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5444	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	IMDSOFT - METAVISION CIS K012349
2013-5445	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	PICIS - WEIGHT BASED DOSE CONVERTER K121542
2013-5446	07/16/2013 08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS J OSTROWSKI Draeger Medical Systems Inc	CERNER CARE - AWARE IBUS K093134
2013-5447	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	CAROLINA MEDICAL - TRIAMCINOLONE ACETONIDE ANDA 89-595 SBA
2013-5448	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	CAROLINA MEDCL - TRIAMCINOLONE ACETONIDE ANDA 89-595 SBA
2013-5449	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - TRIAMCINOLONE ACETONIDE ANDA 87-385 SBA
2013-5450	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - TRIAMCINOLONE ACETONIDE ANDA 87-357 SBA
2013-5451	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	PERRIGO NEW YORK - TRIAMCINOLONE ACETONIDE ANDA 87-356 SBA
2013-5452	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	FOUGERA PHARMS - TRIAMCINOLONE ACETONIDE ANDA 85-692 SBA
2013-5453	07/17/2013	FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN	TARO - NYSTATIN & TRIAMCINOLONE ACETONIDE ANDA

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	08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DR REDDY'S LABORATORIES INC	62-364 SBA
2013-5454	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	TARO - NYSTATIN & WTRIAMCINOLONE ACETONIDE ANDA 63-305 SBA 3/29/93
2013-5455	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	TARO - NYSTATIN ANDA 64-022 SBA
2013-5456	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LALITHA SUBRAMANIAN DR REDDY'S LABORATORIES INC	FOUGERA PHARMS - NYSTATIN ANDA 62-124 SBA
2013-5457	07/17/2013 08/14/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DAVID SCOTT BLUE ZETETIC	BOXES FOR HAIR SHAMPOO & CONDITIONERS 8, 21 PALLET'S ENTRY NUMBER EHP00774480 - PHOTOGRAPHS, OASIS COMPUTER DATA BASE SCREEN SHOTS
2013-5458	07/17/2013 08/14/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	DONALD N BLUE ZETETIC INC	SEXY HAIR CONCEPTS ENTRY #3HP00774480 - RECS
2013-5459	07/17/2013 08/14/2013	FDA/OC/OES/	MOTEN, LAVEETA D	LISTING OF DATES IN HOURS, MINS THAT LAVEETA D MOTEN WAS LOGGED ON TO THE HHS, FDA, OMS, CFSAN COMPUTER SYS AFTER 4:30 PM MONDAY THROUGH FRIDAY ON LEGAL HOLIDAYS, & ON WEEKENDS 1/1/11- 8/14/11
2013-5460	07/17/2013 08/14/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	LISTING OF ALL DATES IN HOURS , MINS LAVEETA D MOTEN WAS LOGGED ON TO THE HHS, FDA, OMS, CFSAN COMPUTER SYS AFTER 4:30 PM MONDAY THROUGH FRIDAY, ON LEGAL HOLIDAYS & ON WEEKENDS 12/5/11 TO 6/30/12
2013-5461	07/17/2013 08/14/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	LISTING OF ALL DATES HOURS & MINS THAT LAVETTA D MOTEN WAS LOGGED ON TO THE HHS, FDA, OMS, CFSAN COMPUTER SYS AFTER 4:30 PM MONDAY THROUGH FRIDAY, ON LEGALL HOLIDAYS & WEEKENDS 7/1/10- 12/31/10
2013-5462	07/17/2013 08/14/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE-	ANDREW HACK MILLENNIUM MANAGEMENT LLC	MANNKIND CORP, VALENCIA, CA, PARAMUS, NJ, DANBURY, CT - EIRS, 483S, UNTITLED LTRS 1/12 TO PRESENT

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		DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/		
2013-5463	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK MILLENNIUM MANAGEMENT LLC	DR JANET WOODCOCK OFFICE OF STRATEGIC PROGRAMS, OFFICE OF HEALTH & CONSITUENT AFFAIRS, PARENT PROJECT MUSCULAR DYSTROPHY - MEETING 7/9/13
2013-5464	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	APRVD DRUG PRODS LISTED BY ACTIVE INGREDIENT
2013-5465	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHELLE WILSON VIRTUAL REGULATORY SOLUTIONS	MENADIONE - NDA 02-139 NON-CLNCL, CLINICAL SAFETY RECS SBA
2013-5466	07/17/2013 08/14/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SMITHKLINE BEECHMAN (CORK) LTD DBA GLAXOSMITHKLINE -AVANDAMET (METFORMIN HCL ROSIGILTAZONE MALEATE) NDA 21-410/032, APRVL PKG 1/25/13
2013-5467	07/17/2013 08/14/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEMP LITTLE KEMP LITTLE LLP	ALLERGAN INC - LATISSE CLNCL INVESTIGATIONS, STUDIES, OPTHALMIC DRUGS A/C 12/5/08
2013-5468	07/17/2013 08/14/2013	OC/OCC/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BAYER, RANGE RICHARD D	DECLARATION OF MARY T CARDEN - TABS 55-63, EXHIBITS 274, 275
2013-5469	07/17/2013 08/14/2013	FDA/OF/CFSAN/OCD/EOS/	JOHN H COX INTERNATIONAL ASSOCIATION OF COLOR MANUFACTURERS	FRUIT JUICE OR VEGTABLE JUICE - OPINIONS 6/25/08; GNT USA INC - SPIRULINA CONCENTRATE PETITION
2013-5470	07/17/2013 08/14/2013	CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	ZILPATEROL HCL (ZILMAX) TYPE C MEDICATED FEED NADA 141-258 - ANALYTICAL METHODS
2013-5471	07/17/2013 08/14/2013	FDA/OMPT/CTP/OD/	NATALIE N SANDERS LATHAM & WATKINS LLP	FOUR NEW TOBACCO PRODS - COMM RELATING TO THE NON SUBSTANITALLY EQUIALENT DETERMINATIONS WITHOUT LIMITATIONS, COMM TO APRVL OR DENIAL OF

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				THE SUBSTANTIAL EQUIVALENCE SUBMISSIONS
2013-5472	07/17/2013 08/14/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ ORA/ORO/DFS/ ORA/ORO/DFS/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	NICHOLAS J PAROLISI LITCHFIELD CAVO LLP	E COLI 0121 MUTISTATE OUTBREAK - LINE LISTS, CORR, EMAILS, ETC 12/20/12 TO 4/15/13
2013-5473	07/17/2013 08/14/2013	FDA/OF/CFSAN/OCD/EOS/	CASSELLS B-8317 T-20, KEITH M	SOY & SOY PRODS EFFECTS
2013-5474	07/17/2013 08/14/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Russ Garrison Garrison, Russell	VERATHON INC, BOTHELL, WA - EIR (10/01/2012 - 07/01/2013)
2013-5475	07/18/2013 08/15/2013		MATT SMITH MATT SMITH	DKT 1995N-0259
2013-5476	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	NDA 019048 - SBA
2013-5477	07/18/2013 08/15/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Michael Atkins Atkins Intellectual Property, PLLC	BQL-0015477-1/1/5; BQL-0015477-1/1/9; BQL-0017148-6/1/5; ETC
2013-5478	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicole Larch Sandberg, Phoenix and vonGontard	BENTYL, DICYCOLMINE HYDROCHLORIDE - MEDWATCH RPTS
2013-5479	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael R. Liepman, M.D. Western Michigan University School of Medicine, Department of Psychiatry, Research Division	SUMMARY OF DATA SUPPORTING BLACK BOX HEPATOXICITY WARNING ON ORAL NALREXONE

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2013-5480	07/18/2013 08/15/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	T. Christian Miller PROPUBLICA	JOHNSON & JOHNSON, HORSHAM, PA - INSPECTION RECS APRIL 2011
2013-5481	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Beau Bassett Pura Vida Investments	9284733 9292050 9299545 ETC
2013-5482	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ivan Poullaos, for Watson Laboratories, Inc. WINSTON & STRAWN LLP	MYLAN TECHNOLOGIES, MYLAN PHARMACEUTICALS, INC, MYLAN INC - 180 DAY MARKET EXCLUSIVITY FOR GENERIC VERSION OF LIDODERM
2013-5483	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 203263 - SBA
2013-5484	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K040395
2013-5485	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	NDA 50718 S002
2013-5486	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Garth Conrad Medtronic Spinal & Biologics	MEDTRONIC SOFAMOR DANEK GMBH, DEGGENDORF, GERMANY - EIR (03/01/2011 - 07/30/2010)
2013-5487	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Scott hodes Scott A. Hodes, Attorney at Law	SPRYCEL, TASIGNA, GLEEVEC - AERS
2013-5488	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	James Barton Herbalife International of America, Inc.	NINGBO ZHENHAI HAIDE BIOCHEM, CHINA - 483 (01/01/2012 - 07/15/2013)
2013-5489	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	NDA 50718 - SBA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-5490	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Lee RICHARD LEE COBB & HALL	HUMIRA - AERS
2013-5491	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Lee RICHARD LEE COBB & HALL	STELARA - AERS
2013-5492	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Greg Clark Clark, Greg B	K837494
2013-5493	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Lee RICHARD LEE COBB & HALL	EMBREL - AERS
2013-5494	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	EDECIN - SBA
2013-5495	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K093397
2013-5496	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	HUMIRA - STABILITY/TEMPERATURE EXCURSION INFORMATION
2013-5497	07/18/2013 08/15/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Rachael Tanner Rachael Tanner	K050783
2013-5498	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 202379 S005
2013-5499	07/18/2013	FDA/OMPT/CDER/GRP/DIDP/	Nancy Kotlowski	HUMIRA - AERS

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	08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Baxter Baker Siddle Conn & Jones, LLP	
2013-5500	07/18/2013 08/15/2013	FDA/OO/OHR/ FDA/OF/CFSAN/OCD/EOS/	Cheryl Stevens Stevens, Cheryl L	INDIVIDUAL RECS
2013-5501	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	NDA 019117, S012 - SBA
2013-5502	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	ANDA 072494 - SBA
2013-5503	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	ANDA 063305 - SBA
2013-5504	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W LABORATORIES INC	ANDA 062364
2013-5505	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bret Andrte EyeReg Consulting, Inc.	K980818
2013-5506	07/18/2013 08/15/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Marilee Kartje Teva Pharmaceuticals	GENZYME, ALLSTON, MA - RESPONSE TO 483 (10/01/2009 - 10/31/2010)
2013-5507	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Dunlap Alpert Medical School of Brown University	MIRENA IUD - CLINICAL TRIAL DATA; BURLEX - POSTMARKET STUDY; MIRENA PERFORATION AND MIGRATION RATES ETC
2013-5508	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Higgins Highline Research Advisors	EXUBERA, HUMALOG, NOVOLOG - AERS

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2013-5509	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INVESTIGATION RECS
2013-5510	07/18/2013 08/15/2013	FDA/OF/CFSAN/OCD/EOS/	Stephen Gardner The Center for Science in the Public Interest	BAYER DIETARY SUPPLEMENTS - AERS
2013-5511	07/18/2013 08/15/2013	FDA/OC/OES/DDM/	Freddy Mejia Ansell Healthcare Products LLC	DKT 75N-0183
2013-5512	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BIOPHOSPHONATES - MEDICATION GUIDES
2013-5513	07/18/2013 09/10/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	BAYER, BERKELEY, CA - EIR 8/11
2013-5514	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	IBANDRONATE - MEDICATION GUIDE
2013-5515	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Pamela miller Pamela Miller	INDIVIDUAL RECS
2013-5516	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Antonei B. Csoka, Ph.D. HOWARD UNIVERSITY	SSRI, SNRI MEDICATIONS - SEXUAL AERS
2013-5517	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Remington Lee Nevin Johns Hopkins Bloomberg School of Public Health	OTSG CORR WITH FDA RE WITHDRAWAL OF NDA 019578
2013-5518	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ben Joseph Rice Voelker	CORR BTWN FDA/MEDSUN AND INTUITIVE SURGICAL RE SMALL SAMPLE SURVERY OF DA VINCI SURGICAL SYSTEM (01/01/2013 - 07/17/2013)
2013-5519	07/18/2013	FDA/OGROP/ORA/CE-FO/CHI-	David Mangione	CSL BEHRING LLC, BRADLEY, IL - EIR, 483 (05/30/2013 -

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	08/15/2013	DO/CHI-CB/	Govzilla, Inc.	05/30/2013)
2013-5520	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JANICE M. HOGAN HOGAN LOVELLS US LLP	BLUESHINE - GOLD SERIES LASER DVC K110375
2013-5521	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	JANICE . HOGAN HOGAN LOVELLS US LLP	CUTERA - GENESIS PLUS LASER SYS K103626
2013-5522	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAICE M. HOGAN HOGAN LOVELLS US LLP	PINPOINTE - FOOTLASER DVC K093547
2013-5523	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	LEWIS T. STONEBURNER CANTOR STONEBURNER ET AL	PENISULA KIDNEY ASSOCIATES PC, HAMPTON, VA; VASCULAR ACCESS CENTER, HAMPTON, VA - MEDCOMP OR BARD QUINTON CATHETER MEDWATCH RPT 9/7/10
2013-5524	07/18/2013 08/15/2013	FDA/OF/CFSAN/OCD/EOS/	SEAN HIGGINS, Esq. ANDREWS & THORNTON	JACK 3D, OXY ELITE PRO, NUTREX LIPO 6 BLACK PRODUCTS, ETC - CAERS 12/17/12 TO PRESENT
2013-5525	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SEAN HIGGNINS, Esq. ANDREWS & THORNTON	FORTHANE - NDA, APRVL
2013-5526	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	BRUCE SHERMAN, RN Vistakon	VISTAKON - MW5020993
2013-5527	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	BRUCE SHERMAN, RN Vistakon	VISTAKON - MW5023889
2013-5528	07/18/2013 08/15/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	WALTER E. CHALKLEY THOMSON REUTERS	MARKSANS PHARMACEUTICALS LTD, COMMACK, NY - EIR, 483, CO RESP 1/26/12
2013-5529	07/18/2013 08/15/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	WALTER E. CHALKLEY THOMSON REUTERS	OTSUKA AMERICA PHARMACEUTICAL INC, ROCKVILLE, MD - EIR, 483, CO RESP 7/20/12
2013-5530	07/18/2013 08/15/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	PHARMALUCENCE INC, BILLERICA, MA - CO RESP, EIR, 483 3/13/12
2013-5531	07/18/2013 08/15/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	LANNETT CO INC, PHILADELPHIA, PA - CO RESP, EIR, 483 8/17/12
2013-5532	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	US GENERICS PROGRAM, BARRANQUILLA, COLOMBIA - CO RESP, EIR, 483 6/22/12
2013-5533	07/18/2013 08/15/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	US GENERICS PROGRAM, BARRANQUILLA, COLOMBIA - CO RESP, EIR, 483 6/22/09

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-5534	07/18/2013 08/15/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E. CHALKLEY THOMSON REUTERS	FRESENIUS KABI USA LLC, SCHAUMBURG, IL - EIR, 483, CO RESP 5/4/12
2013-5535	07/18/2013 08/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	B BRAUN MEDICAL INC, IRVINE, CA - EIR, 483, CO RESP 3/8/12
2013-5536	07/18/2013 08/15/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E. CHALKLEY THOMSON REUTERS	APRIA HEALTHCARE INC, FIFE, WA - EIR, 483, CO RESP 2/7/12
2013-5537	07/18/2013 08/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMPHASTAR PHARMACEUTICALS INC, RANCHO CUCAMONGA, CA - EIR, 483, CO RESP 6/28/12
2013-5538	07/18/2013 08/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E. CHALKLEY THOMSON REUTERS	AMAG PHARMACEUTICALS INC, CAMBRIDGE, MA - CO RESP, EIR, 483 5/24/12
2013-5539	07/18/2013 08/15/2013	OC/OL/	JONES, THOMAS H	SENATOR MARY PRYOR - CORR
2013-5540	07/18/2013 08/15/2013	FDA/OF/CFSAN/OCD/EOS/	MITCHELL A CHESSEMAN, Ph.D. STEPTOE & JOHNSON	FCN 1072
2013-5541	07/18/2013 08/15/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	LIZ SZABO USA TODAY	STANISLAW BURZYNSKI, RASHID BUTTAR, JOSEPH MERCOLA - WARNING LTRS
2013-5542	07/18/2013 08/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL R. MCCARTHY PARSONS BEHLE & LATIMER	SYNTHES - VARIABLE ANGLE FOREFOOT MIDFOOT SYS K100776
2013-5543	07/18/2013 08/15/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JORDAN HILL COHEN MILSTEIN HAUSFELD & TOLL	IMPAX LABORATORIES INC & FDA - MEMOS, INSPECTOR NOTES, EMAILS, ETC

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2013-5544	07/18/2013 08/16/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	DONALD BLUE GLOBAL TRADE INTELLIGENCE INC	IMPORTS FROM 6/16/13 TO 7/13/15
2013-5545	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MASSIMO CALAFIORE FACET-LINK INC	LIMACORPORATE SPA - DELTA TT ACETABULAR SYS K112898
2013-5546	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MASSIMO SALAFIORE FACET-LINK INC	EXACTECH INC - NOVATION EMPIRE ACETABULAR AUGENTS WITH INTEGRIP DVC K101761
2013-5547	07/19/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	SANDRA LITAO, DASMARINAS, PHILLIPPINES - EIR, 483, CO RESP 7/6/12
2013-5548	07/19/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	WALTER E CHALKLEY THOMSON REUTERS	UERM MEMORIAL MEDI, QUEZON, PHILLIPPINES - EIR, 483, CO RESP 6/29/12
2013-5549	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	ROCHE DIAGNOSTICS GMBH, PENZBERG, GERMANY - EIR, 483, CO RESP 10/16/12
2013-5550	07/19/2013 08/16/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	LINCARE INC, PORT ANGELES, WA - EIR, 483, CO RESP 4/16/12
2013-5551	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	LABORATORIOS GRIFOLS SA, BARCELONA, SPAIN - EIR, 483, CO RESP 7/11/12
2013-5552	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	EXEMPLAR PHARMACEUTICALS LLC, FALL RIVER, MA - EIR, 483, CO RESP 2/15/13
2013-5553	07/19/2013	FDA/OGROP/ORA/SW-FO/DEN-	WALTER E CHALKLEY	EXEMPLA INC (DBA EXEMPLA LUTHERAN MEDICAL

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	08/16/2013	DO/DEN-CB/	THOMSON REUTERS	CENTER), WHEAT RIDGE, CO - EIR, 483, CO RESP 1/14/13
2013-5554	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	JANET K TILLISCH MD, FARGO, ND - EIR, 483, CO RESP 4/9/13
2013-5555	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	XANODYNE PHARMACEUTICALS INC, NEWPORT, KY - EIR, 483, CO RESP 3/30/12
2013-5556	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, 483, CO RESP 1/27/12
2013-5557	07/19/2013 08/16/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ORTHO BIOLOGICS LLC, MANATI, PR - EIR, 483, CO RESP 2/14/13
2013-5558	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	OHM LABORATORIES INC, NEW BRUNSWICK, NJ - EIR, 483, CO RESP 12/18/12
2013-5559	07/19/2013 08/16/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	NEW YORK BLOOD CENTER INC, NEW YORK, NY - EIR, 483, CO RESP 1/15/13
2013-5560	07/19/2013 08/16/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	NEPHRON PHARMACEUTICALS CORP, ORLANDO, FL - EIR, 483, CO RESP 8/17/12
2013-5561	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NATIONWIDE CHILDREN'S HOSPITAL IRB, COLUMBUS, OH - EIR, 483, CO RESP 1/25/13
2013-5562	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDI PHYSICS INC (DBA GE HEALTH CARE INC), SOUTH PLAINFIELD, NJ - EIR, 483, CO RESP 1/9/13
2013-5563	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDEFIL INC, GLENDALE HEIGHTS, IL - EIR, 483, CO RESP 5/25/12
2013-5564	07/19/2013 08/16/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ST LUKE'S HOSPITAL BLOOD BANK, KANSAS CITY, MO - EIR, 483, CO RESP 3/13/13
2013-5565	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	SGS LIFE SCIENCE SERVICES, WEST CHESTER, PA - EIR, 483, CO RESP 3/6/13
2013-5566	07/19/2013 08/16/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	QUALIMAX LLC, RIDGEFIELD, NJ - EIR, 483, CO RESP 3/6/13
2013-5567	07/19/2013 08/16/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Liz Szabo USA TODAY	BURZYNSKI - ADVERSE EVENTS

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2013-5568	07/19/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PLASMACARE INC, CLEVELAND, OH - EIR, 483, CO RESP 1/31/13
2013-5569	07/19/2013 08/16/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Liz Szabo USA TODAY	BURZYNSKI RESEARCH INSTITUTE, HOUSTON, TX - INSPECTION REPORTS, CORR (01/01/2001 - 07/17/2013)
2013-5570	07/19/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	TISHCON CORP, SALISBURY, MD - EIR, 483, CO RESP 1/30/13
2013-5571	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Claus Fuxen Siegfried AG	SIEGFRIED MALTA LTD, MALTA - QAP
2013-5572	07/19/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OF/CFSAN/OCD/EOS/	Boris Friedman Kline & Company	ABBOTT NUTRITION, TIPP CITY, OH - EIR (01/01/2013 - 07/19/2013)
2013-5573	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL ROBOTS - RESULTS FROM SURGEON SURGEY
2013-5574	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Madhav Kamat Ursam Pharma LLC	08P-0591/CP1 - SBA
2013-5575	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Peter Anderson Ashcraft& Gerel	K011071, K070430, P98002
2013-5576	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	STERIS ISOMEDIX SERVICES, NORTHBOROUGH, MA - EIR, 483, CO RESP 1/4/13
2013-5577	07/19/2013 08/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	UNIV OF CALIFORNIA, SAN DIEGO, CA - EIR, 483, CO RESP 1/15/13
2013-5578	07/19/2013 08/16/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	WAYNE CONCEPT MANUFACTURING CO INC, FORT WAYNE, IN - EIR, 483, CO RESP 1/10/13
2013-5579	07/19/2013 08/16/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	VISTAPHARM INC, LARGO, FL - EIR, 483, CO RESP 6/15/12

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		FDA/OC/OES/DFOI/		
2013-5580	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	VERTEX PHARMACEUTICALS INC, CAMBRIDGE, MA - EIR, 483, CO RESP 8/2/12
2013-5581	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SANDOZ GMBH, LANGKAMFEN, AUSTRIA - EIR, 483, CO RESP 3/16/12
2013-5582	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER INC, PEARL RIVER, NY - EIR, 483, CO RESP 10/24/12
2013-5583	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	ALBANY MEDICAL CENTER HOSPITAL BLOOD BANK, ALBANY, NY - EIR, 483, CO RESP 1/14/13
2013-5584	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	NEXTWAVE PHARMS - QUILLIVANT XR (METHYLPHENIDATE HCL) NDA 202-100/S001 APRVL LTR
2013-5585	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neal Wadhwa Partner Fund Management	AGILA, INDIA - 483 (07/01/2003 - 07/19/2013)
2013-5586	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Carol Wasteneys The Mentholatum Company	TOPICAL SKIN BLEACHING DRUG PRODUCTS CONTAINING 2% AND 4% HYDROQUINONE
2013-5587	07/19/2013 08/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ira Matthew Mains Offutt Nord Burchett, PLLC	KETOROLAC TROMETHAMINE 30 MG/ML CONCENTRATION - APPROVED PACKAGE INSERTS
2013-5588	07/19/2013 08/16/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lauren Miller Miller, Lauren	FRUCTOSIN - ALL RECS
2013-5589	07/19/2013	ORA/ORM/	David Mangione	LIST OF INSPECTIONS 06/22/2013 - 07/17/2013

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	08/16/2013	ORA/ORM/	Govzilla, Inc.	
2013-5590	07/19/2013 08/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K082423
2013-5591	07/19/2013 08/16/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Mary A. Matthew, Vice President Regulatory Affairs ZIOPHARM Oncology	ZIOPHARM - COMPLAINTS
2013-5592	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 125288 - CHECKLIST
2013-5593	07/22/2013 08/19/2013	FDA/OF/CFSAN/OCD/EOS/	John Blackwell RICHMOND TIMES-DISPATCH	ANATABLOC - AERS
2013-5594	07/22/2013 08/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K090915
2013-5595	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2008-2174
2013-5596	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	CHRISTOPHER SZECHENYI ONE POINT INVESTIGATIONS	OMONTYS - AERS
2013-5597	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	BEN ELGIN BLOOMBERG NEWS	RACTOPAMINE - AERS 1/1/03 TO 7/13/13
2013-5598	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	BEN ELGIN BLOOMBERG NEWS	ZILPATEROL - AERS 1/1/03 TO 7/17/13
2013-5599	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	BEN ELGIN BLOOMBERG NEWS	CARBADOX - AERS 1/1/03 TO 7/17/13

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2013-5600	07/22/2013 08/19/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	INTUITIVE SURGICAL - COVER LTRS FOR COMPANIES THAT FILED FOIA REQUESTS 2013
2013-5601	07/22/2013 08/19/2013	FDA/OC/OES/ FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	INTUTIVE SURGICAL - 2012-2367, 2012-2875, 2012-4606, ETC COVER LTRS
2013-5602	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165500 - ADDITONAL RECS
2013-5603	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 165504 - ADDITIONAL RECS
2013-5604	07/22/2013 08/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NYROBIA FREEMAN CONMED LINVATEC CORP	ARTHREX INC, NAPLES, FL - MIXING & DELIVERY SYS K121124
2013-5605	07/22/2013 08/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	JACQUELINE J CHAN K&L GATES	NEBA HEALTH LLC - NEUROPSYCHIATRIC COMPACT EEG SYS ASSESMENT AID SUBMISSIONS, PETITIONS, CORR, ETC 7/15/13
2013-5606	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DENIS VANNESS VANNESS & VANNESS PA	AMBIEN (ZOLPIDEN TARTRATE) - AERS
2013-5607	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	TORRENT PHARMS, KALAMAZOO, MI - ZOLPIDEM TARTARATE AERS
2013-5608	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRIDE#320426, PHILIP	MARIJUANA, PSYCHADELIC MSHROOMS, METH, ETC - AERS
2013-5609	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MEREDITH N REINHARDT DRINKER BIDDLE REATH LLP	EIL LILLY & CO - ZPREXA LTRS 1/12/07, 2/20/07, 3/28/07, ETC

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5610	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CELGENE CORP - FOCALIN (DEXMETHYLPHENIDATE HCL) NDA 21-278/001 APRVL LTR LBLG 1/03/02
2013-5611	07/22/2013 08/19/2013	FDA/OF/CFSAN/OCD/EOS/	ANNE SHEROD LEAVITT PARTNERS	LUBRIIZO CORP - FCN 148
2013-5612	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/24-28/13
2013-5613	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/24-28/13
2013-5614	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/24-28/13
2013-5615	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 6/24-28/13
2013-5616	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	KENNETH TEID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 6/24-28/13
2013-5617	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 6/17-21/13
2013-5618	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 6/17-21/13
2013-5619	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 6/17-21/13
2013-5620	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 6/17-21/13
2013-5621	07/22/2013 08/19/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	DEMENT-MYERS, PATRICIA A	CMPLNT 131784
2013-5622	07/22/2013	FDA/OF/CFSAN/OCD/EOS/	PAULINA DO	ADEKA CORP - FCN 719

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	08/19/2013		EXPONENT, INC.	
2013-5623	07/22/2013 08/19/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ANNE KERR B & A BROKERS INC	OCEAN PREMIUM INC - AHS-0146103-4 LAB RPTS
2013-5624	07/22/2013 08/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESTER GIBBS ACTELION CLINICAL RESEARCH INC	TEMODAR (TEMOZOLOMIDE) CAPS NDA 21-029/S008 SUMMARY, ASSESSMENT
2013-5625	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 7/1-5/13
2013-5626	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/24-28/13
2013-5627	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/17-21/13
2013-5628	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	FOI DAILY LOG 6/10-14/13
2013-5629	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	FOI DAILY LOG 7/1-5/13
2013-5630	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	FOI DAILY LOG 7/1-5/13
2013-5631	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	DEBRA L COHEN WOLTERS KLUWER LAW & BUSINESS	FOI DAILY LOG 7/1-5/13
2013-5632	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	FOI DAILY LOG 7/1-5/13
2013-5633	07/22/2013 08/19/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	FOI DAILY LOG 7/1-5/13
2013-5634	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Franolic VERSAPHARM INCORPORATED	ANDA 040771 - SBA
2013-5635	07/23/2013	FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16)	8334428 8341524 8344995 ETC

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	08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MERCK & CO., INC.	
2013-5636	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	David Mangione Govzilla, Inc.	COOK PHARMACIA LLC, BLOOMINGTON, IN - EIR, 483 (06/17/2013 - 06/17/2013)
2013-5637	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K960009
2013-5638	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K946109
2013-5639	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael R. Liepman, M.D. Western Michigan University School of Medicine, Department of Psychiatry, Research Division	REVIA, NALTREXONE HYDROCHLORIDE - AERS
2013-5640	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Lee Kevin Lee	K081307
2013-5641	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jason Kantor CREDIT SUISSE	ADCETRIS - AERS
2013-5642	07/23/2013 08/20/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alex Nussbaum HEALTHCOR MANAGEMENT LP	AKORN - 483 (07/01/2010 - 07/19/2013)
2013-5643	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	CASE NUMBER 8563296

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5644	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom DeLong UNIVAR USA INC	RHODIA POLIAMIDE E ESPECIALIDADES, SAO PAULO, BRAZIL - EIR (03/01/2012 - 10/02/2012)
2013-5645	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8360804 8430873 8444923 ETC
2013-5646	07/23/2013 08/20/2013	CVM/OCD/	Stephanie Markey Dechra Development LLC	NADA 140474 - ORIGINAL FOIA SUMMARY
2013-5647	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8340068 8429241 8447180 ETC
2013-5648	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	8322581 8358217 8431576 ETC
2013-5649	07/23/2013 08/20/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	David L. Shulman Law Office of David L. Shulman PLLC	GO FRESH, MINNEAPOLIS, MN - ALL RECS RE FDA, MN DEPT OF AGRICULTURE INSPECTION
2013-5650	07/23/2013 08/20/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	David Mangione Govzilla, Inc.	GENENTECH, OCEANSIDE, CA - EIR, 483 (05/23/2013 - 05/23/2013)
2013-5651	07/23/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jonathan Klein Sullivan & Associates, LLC	DEPUY HIP IMPLANTS - AERS, WARNING LETTERS, COMPLIANCE ACTIONS ETC
2013-5652	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K932293
2013-5653	07/23/2013 08/20/2013	FDA/OO/OFBA/OAGS/	Rose Santos FOIA Group, Inc.	HHSF22301003T, HHSF22301004T - TASK ORDERS, MODIFICATIONS
2013-5654	07/23/2013	FDA/OMPT/CDER/GRP/DIDP/	Michelle Elizabeth Legiec	CIPLA LIMITED, INDIA - INSPECTION RECS (04/01/2013 - 06/30/2013)

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	08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eagle Pharmaceuticals, Inc.	
2013-5655	07/23/2013 08/20/2013	FDA/OO/OFBA/OAGS/	Nafisah Ula AFL-CIO	CONTRACTS BETWEEN FDA AND BARWOOD TAXI (01/01/2000 - 07/19/2013)
2013-5656	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	ARCAPTA NEOHALE, BENLYSTA, HORIZANT ETC - MINUTES FROM PRE-NDA MEETINGS
2013-5657	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	EYLEA, ARCAPTA NEOHALER, GADAVIST ETC - ACTION CHECKLISTS
2013-5658	07/23/2013 08/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ed Takken Self	NEBA COMACT EEG SYSTEM - DE NOVO APPLICATION
2013-5659	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Inst. Cent. For Med. Media.	XANAX - MEDICAL REVIEW FROM ORIGINAL APPROVAL
2013-5660	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	ARICEPT - P 56, 57 OF STATISTICAL REVIEW
2013-5661	07/23/2013 08/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jun Wu Astellas Scientific and Medical Affairs	GILOTRIF - SAFETY AND EFFICACY DATA
2013-5662	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 6/16-14/13
2013-5663	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 6/10-14/13
2013-5664	07/23/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN	DAILY LOG 6/10-14/13

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	08/20/2013		Center for Regulatory Services, Inc.	
2013-5665	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 6/10-14/13
2013-5666	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 6/17-21/13
2013-5667	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 6/24-28/13
2013-5668	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/1-5/13
2013-5669	07/23/2013 08/20/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	Anna Edney BLOOMBERG NEWS	MERCK - 483, WARNING LETTER RE SUGAMMADEX STUDY (01/01/2011 - 07/16/2013)
2013-5670	07/23/2013 08/20/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL, SUNNYVALE, CA - WARNING LETTER (06/01/2013 - 07/19/2013)
2013-5671	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/10-14/13
2013-5672	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/17-21/13
2013-5673	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 6/24-28/12
2013-5674	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/1-5/13
2013-5675	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 6/10-14/13
2013-5676	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 6/17-21/13
2013-5677	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 6/24-28/13
2013-5678	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 7/1-5/13
2013-5679	07/23/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	DAILY CLOSED LOG 6/10-14/13

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	08/20/2013		CanReg, Inc.	
2013-5680	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 6/17-21/13
2013-5681	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 6/10-14/13
2013-5682	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 6/24-28/13
2013-5683	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/1-5/13
2013-5684	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/24-28/13
2013-5685	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/17-21/13
2013-5686	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 6/10-14/13
2013-5687	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/17-21/13
2013-5688	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/24-28/13
2013-5689	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 6/10-14/13
2013-5690	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 7/1-5/13
2013-5691	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/1-5/13
2013-5692	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/10-14/13
2013-5693	07/23/2013 08/20/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 6/17-21/13
2013-5694	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K121498
2013-5695	07/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA	K110943

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	08/21/2013		BIO TEX INC	
2013-5696	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER-INGELHEIM, AUSTRIA - EIR 4/13
2013-5697	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	BOEHRINGER-INGELHEIM, AUSTRIA - 483 4/13
2013-5698	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	APOTEX INC- LATANOPROST OPTHALMIC SOL ANDA 77-697 SUPPL, AMENDMENTS, COMM, ETC
2013-5699	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	ALCON - LATANOPROST OPTHALMIC SOL ANDA 91-449 SUPPL, AMENDMENTS, COMM, ETC
2013-5700	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	LUITPOLD PHARMACEUTICALS INC (AMERICAN REGENT INC) - LATANOPROST OPTHALMIC SOL ANDA 200-925 SUPPL, AMENDMENTS, COMM, ETC
2013-5701	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	MYLAN PHARMACEUTICALS INC - LATANOPROST OPTHALMIC SOL ANDA 201-786 SUPPL, AMENDMENTS, COMM, ETC
2013-5702	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	JOHN C THORNTON ANDREWS & THORNTON	DR REEDY'S LABS LTD - LATANOPROST OPTHALMIC SOL ANDA 202-077 SUPPL, AMENDMENTS, COMM, ETC
2013-5703	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN C THORNTON ANDREWS & THORNTON	BAUSCH & LOMB PHARMACEUTICALS INC - LATANOPROST OPTHALMIC SOL ANDA 201-006 SUPPL, AMENDMENTS, COMM, ETC

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		FDA/OMPT/CDER/ORP/DIDP/		
2013-5704	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SCALIA, TONI	CLOZARIL - AERS
2013-5705	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	FARHAD GHANI OPTIMA HEALTH SOLUTIONS INTERNATIONAL CORP	K060043 - CLEARANCE LTR
2013-5706	07/24/2013 08/21/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ CVM/OC/	SHEDD, PATTI	SPL 787480, 787481 - TEST RESULTS
2013-5707	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	NEISWONGER, LAURA	ATENOLO - AERS 2012 TO PRESENT
2013-5708	07/24/2013 08/21/2013	FDA/OF/CFSAN/OC/EO/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	MCCORMICK POLSKA SA - EIR
2013-5709	07/24/2013 08/21/2013	FDA/OC/OES/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ ORA/OC/ ORA/OC/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	PAULA RAMER KAYE SCHOLER LLP	2007-2093, 2007-3834, 2007-7689, ETC
2013-5710	07/24/2013 09/13/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CATHERINE A HAY MASSBIOLOGICS	MASSBIOLOGICS (MASSACHUSETTS PUBLIC HEALTH BIOLOGIC LABS) - PERTUSSIS IMMUNE GLOBULIN INTRAVENOUS BB-IND-4465 RECS

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2013-5711	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ OC/OCC/ ORA/ ORA/	ANGELA J MASON COCHRAN FIRM-DOTHAN PC	MAIN STREET FAMILY PHARMACY, NEWBERN, TN - INVESTIGATIONS; INDIVIDUAL RECS
2013-5712	07/24/2013 08/21/2013	FDA/OF/CFSAN/OCD/EOS/	FARINA ASLAM Keller and Heckman LLP	TESTING FOR ORGANIC AND INORGANIC ARSENIC IN RICE AND RICE PRODS 1991 TO PRESENT
2013-5713	07/24/2013 08/21/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLCORD, JARD S	PEREGRINE PHARMS - BAVITUXIMAB (DOCETAXEL) FINALIZED END OF PHASE TWO MEETING MINS, CALANDER DATE
2013-5714	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANNMARIE BROWN-JIMENEZ JOSEPH M LICHTENSTEIN PC	KARL STORZ ENDOSCOPIC DVC - RPT 10/22/07
2013-5715	07/24/2013 08/21/2013	FDA/OC/OES/DFOI/	ELLIOT FAVUS MD FAVUS INSTITUTIONAL RESEARCH LLC	PINNACLE MEDICARE SERVICES - IMPELLA CLNCL DATA, RECS
2013-5716	07/24/2013 08/21/2013	FDA/OC/OES/DFOI/	RISHAR, JOHN	ADDRESSES, NAMES, PHONE NUMBERS OF MFRS OF PERScription MEDICINES SEIZED ON 6/27/13
2013-5717	07/24/2013 08/21/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	CHRISTOPHER VAN GUNDY ROLL LAW GROUP PC	IMPORT ALERT 22-04 - ANALYSIS, TEST RESULTS, CORR, ETC
2013-5718	07/24/2013 08/21/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	BREZA, ANDREW	MELALEUCA INC - RESP TO WARNING LTR 97-NSV-08
2013-5719	07/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA	K093995

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	08/21/2013		BIOTEX INC	
2013-5720	07/24/2013 08/21/2013	FDA/OC/OES/DFOI/	Veronica Moten N.A.	LIST OF EEO COMPLAINTS
2013-5721	07/24/2013 08/21/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Liz Szabo USA TODAY	CORR BTWEEN FDA AND BURZYNSKI RESEARCH INSTITTUE, BURZYNSKI CLINIC, DR BURZYNSKI (06/01/2012 - 07/17/2013)
2013-5722	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K061248
2013-5723	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIOTEX INC	K121479
2013-5724	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA K WOOD SIDLEY AUSTIN LLP	GE HEALTHCARE - OMNISCAN DRUG SAFETY OVERSIGHT BOARD MTG MINS 4/9/07
2013-5725	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REBECCA K WOOD SIDLEY AUSTIN LLP	GE HEALTHCARE - OMNISCAN NDA 20-123/S066 CORR, TELECONFERENCE MINS, ETC 5/1/06 TO 9/30/07
2013-5726	07/24/2013 08/21/2013	CVM/OCD/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	RHOSOPSEUDOMONAS IN BROILER CHICKEN - DAF 02374
2013-5727	07/24/2013 08/21/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OC/OES/DFOI/	JOHN C FISH JAMES DARK & BRILL ATTY AT LAW	PHILIP E MUCCIO, AXIOBIONICS - WEARABKE THERAPY INVESTIGATIONS, VIOLATION, COMPLIANCE RECS, ETC
2013-5728	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	RACHEL ROMAN ESQ ZEVAN & DAVIDSON LAW FIRM LLC	THORATEC - PARACORPOREAL VENTRICULAR ASSIST DVC (PVAD) APRVL RECS, LBLG
2013-5729	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAMELA KOVOCHICH CRIVELLO.CARLSON	OLYMPUS - EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE AND EVIS EXERA II COLONVIDEOSCOPE
2013-5730	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 076278 - SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5731	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	BIOCON LTD, BANGALORE, INDIA - 483 (07/24/2011 - 07/24/2013)
2013-5732	07/24/2013 08/21/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2013-5733	07/24/2013 08/21/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	David Antoon David Antoon	INTUITIVE SURGICAL INC - DIGITAL MARKETING MATERIAL
2013-5734	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 040103 - SBA
2013-5735	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tara Burrell InSitu Technologies, Inc	K961507
2013-5736	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tara Burrell InSitu Technologies, Inc.	K012752
2013-5737	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BRENTUXIMAB - MEDWATCH FORMS
2013-5738	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	BRENTUXIMAB AND PML - MEDWATCH FORMS
2013-5739	07/24/2013	FDA/OMPT/CDER/GRP/DIDP/	Sunil Patel	SANWA KAGAKI KENKYUSHO CO LTD, JAPAN - IND,

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	08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Livwel Therapeutics Inc.	INVESTIGATIONAL BROCHURE, INTERNAL NOTES ETC
2013-5740	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Cathy Shachaf Orlucent	K062092
2013-5741	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa Experien Group, LLC.	K961382, K961383
2013-5742	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Philip Fish Philip Fish	K070210
2013-5743	07/24/2013 08/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 204150 - SBA
2013-5744	07/24/2013 08/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gerard Bencen CONSUMER	K131524, K131009
2013-5745	07/25/2013 08/22/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS - 01/01/2008 TO 07/19/2013
2013-5746	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dan Schreiber Applied Electrodynamics	K833928, K883911
2013-5747	07/25/2013 08/22/2013	FDA/OF/CFSAN/OCD/EOS/	Kenneth Grant Compliance Engineering, Inc.	FCN 852
2013-5748	07/25/2013 08/22/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	Joy Flynn flynn, joy	CELSUS LABORATORIES, INC, CINCINNATI, OH - EIR (01/01/2008 - 07/22/2013)
2013-5749	07/25/2013 08/22/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	b. burgess BURGESS, BERNIE	ORA FINANCIAL RECORD FOR FACTS 808885
2013-5750	07/25/2013 08/22/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	David Antoon David Antoon	INTUITIVE SURGICAL, INC - WARNING LETTER, DOCUMENTATION (07/01/2013 - 07/18/2013)
2013-5751	07/25/2013 08/22/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Kolsky Cohen Milstein Sellers & Toll PLLC	IMPAX LABORATORIES, HAYWARD, CA - EIR, 483 (01/01/2010 - 07/01/2013)

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5752	07/25/2013 09/03/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua Kolsky Cohen Milstein Sellers & Toll PLLC	IMPAX LABORATORIES, HAYWARD, CA - INSPECTION CORR (01/01/2010 - 07/01/2013)
2013-5753	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	NDA 020505/S-042, 020844/S-036
2013-5754	07/25/2013 08/22/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG 07/15/2013 - 07/19/2013
2013-5755	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Alexandra Gatten FORDHAM UNIVERSITY	WORKSHOP ON BATTERY POWERED MEDICAL DEVICES - LIST OF REGISTERED PARTICIPANTS (03/01/2013 - 07/30/2013)
2013-5756	07/25/2013 08/22/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Anita Duncan Reata Pharmaceuticals, Inc.	SCOTT ANTONIA MD, ALBERTO CHIAPPORI, MD, TAWEE TANVETANON - 483, RESPONSE, CORR
2013-5757	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Brian Brockway VivaQuant, LLC	K093288, K072558, K063222
2013-5758	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	George Shamsoun METHAPHARM	PROVOCHOLINE, METHACHOLINE, METHACHOLINE CHLORIDE - AERS
2013-5759	07/25/2013 08/22/2013	FDA/OF/CFSAN/OCD/EOS/	Eric Lim Meng How Crystal Aesthetics	BACTOLAC - REGISTRATION INFORMATION (CERTIFIED)
2013-5760	07/25/2013 08/22/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	TALC IN COSMETICS (CERTIFIED)
2013-5761	07/25/2013 08/22/2013	FDA/OF/CFSAN/OCD/EOS/	Christopher Barnett Chris Barnett	ENERGY DRINKS - FDA GUIDELINES
2013-5762	07/25/2013 08/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CAPT Blane Wilson, USN, RET Wilson, USN, RET , CAPT Blane	IGG/IVIG - AERS
2013-5763	07/25/2013	FDA/OMPT/CDER/GRP/DIDP/	Shin Kang	TECFIDERA - AERS

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	08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WELLS FARGO	
2013-5764	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Robin Primeau MURRAY LAW FIRM	ENDO AND METABOLIC DRUGS ADVISORY COMMITTEE, DRUG SAFETY MANAGEMENT ADVISORY COMMITTEE - PRESENTATION SLIDES, BRIEFING DOCUMENT, ETC (CERTIFIED)
2013-5765	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Robin Primeau MURRAY LAW FIRM	FDA BRIEFING DOCUMENT - AVANDIA NDA 21071
2013-5766	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	Ben Fenner Fredericks Peebles & Morgan LLP	CTP REVIEW, DETERMINATIONS RE NSE (03/22/2011 - 07/23/2013)
2013-5767	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christopher Brennan WESTLAW COURT EXPRESS	ANDA 203257
2013-5768	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick Winn Ra Medical Systems, Inc.	K101599
2013-5769	07/25/2013 08/22/2013	FDA/OO/OHR/ FDA/OO/OHR/ ORA/ ORA/	Roger Farmer NATIONAL TREASURY EMPLOYEES UNION	FLEXIBLE WORKPLACE AGREEMENT
2013-5770	07/25/2013 08/22/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Jane Bentley Alcon Laboratories, Inc.	ALCON LABS, DES PLAINES, IL - EIR (05/06/2013 - 07/19/2013)
2013-5771	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	A. Thomas Doyle Surgical Specialties Corporation	K113004
2013-5772	07/25/2013 08/22/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DDM/	Desmond Jenson Tobacco Control Legal Consortium	FDA-2013-P-0435 - COMMENTS TO DOCKET
2013-5773	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Franolic VersaPharm Inc.	NDA 050689 - SBA
2013-5774	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH WALKER THE WALL STREET JOURNAL	TECFIDERA - AERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-5775	07/25/2013 08/22/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	JOSEPH WALKER WALL STREET JOURNAL	INTUITIVE SURGICAL INC - WARNING LETTER
2013-5776	07/25/2013 08/22/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OC/OES/DFOI/	Jon M. Pellett Barr Murman & Tonelli	MERRILL REUTER, MD, ADVANCED ORTHOPAEDICS - WARNING LETTERS, SANCTIONS, RESPONSES (9/01/2007 - 12/31/2012)
2013-5777	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Michael Basara Epien Medical, Inc.	K903163, K894247
2013-5778	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	WELLBUTRIN - SBA
2013-5779	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 019906 - SBA
2013-5780	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	Matt Mezvinsky RIDGEBACK CAPITAL MANAGEMENT LLC	MITCH ZELLER CONFERENCE CALL RE MENTHOL CIGARETTES - TRANSCRIPT (07/23/2013 - 07/24/2013)
2013-5781	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (06/17/2013 - 06/21/2013)
2013-5782	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	SANDOZ GMBH, AUSTRIA - MOST RECENT EIR
2013-5783	07/25/2013 08/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS
2013-5784	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 075679 - SBA

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2013-5785	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Lando IPNav	CDER MEETING RE THALIDOMIDE - TRANSCRIPT (09/04/1997 - 09/05/1997)
2013-5786	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 3/11/2009 and 3/12/2010 inspections of Sandoz Industrial Products, S.A., Barcelona, Spain
2013-5787	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ORM/ ORA/ORM/	Sandra O'Kelley Merial Limited	LIST OF HUMAN DRUG BIMO INSPECTIONS 01/01/2010 - 07/22/2013
2013-5788	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 5/16/2011 inspection of Laboratoire Unither, ZI de la Guerie, F-50211 COUTANCES Cedex France
2013-5789	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 8/4/2011 inspection of Asahi Glass Co., Ltd. Chiba Plant, 10 Goi-kaigan, Ichihara City, Chiba 290-8566, Japan
2013-5790	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	EIR for NV Organon, MSD, 5340 BH Oss, Netherlands (Issued May 31, 2013)
2013-5791	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	EIR, 483 and all related correspondence for the 3/11/2009 and 3/12/2010 inspections of ZaCh System S.p.A. Via Dovaro 36045 Lonigo Vicenza, ITALY
2013-5792	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robin Primeau MURRAY LAW FIRM	DRUG SAFETY COMMUNICATION - UPDATE TO ONGOING SAFETY REVIEW OF ACTOS ETC (CERTIFIED)

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2013-5793	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robin Primeau MURRAY LAW FIRM	DUETACT, ACTOSPLUS - APPROVAL LETTERS, CHEMISTRY REVIEWS, MEDICAL REVIEWS ETC (CERTIFIED)
2013-5794	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Robin Primeau MURRAY LAW FIRM	ENDO AND METABOLIC DRUGS ADVISORY COMMITTEE - 3/26/99, 4/22/99 TRANSCRIPT (CERTIFIED)
2013-5795	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Nalini Sundaram SNS Biosystems Inc	RAVEN BIOLOGICAL - PRE-AMENDMENT DEVICE EVALUATION APPROVAL DOCUMENTATION
2013-5796	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	ACTIVE REGISTERED BRAND STYLES ISSUED UNDER SECTION 905 OF THE FSPTCA; IDENTITY OF PRODUCTS ISSUED ORDER OF ANNUAL REGISTRATION, MANUFACTURER
2013-5797	07/25/2013 08/22/2013	FDA/OC/OES/DDM/	Nick Gardner The International Food Additives Council	DKT FDA-2013-F-0700, FDA-2013-P-0472
2013-5798	07/25/2013 08/22/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	Hiromi Price Eisai Inc.	ESAI, INC - PREDICT SCORE (01/01/2010 - 06/30/2013)
2013-5799	07/25/2013 08/22/2013	ORA/ORM/ ORA/ORM/	b. burgess BURGESS, BERNIE	LIST OF BIMO INSPECTIONS, PRE-APPROVAL INSPECTIONS CONUDCTED BY LOS-DO IN 2007
2013-5800	07/25/2013 08/22/2013	FDA/OC/OES/ FDA/OGROP/OIP/ FDDA/OMPT/CDER/GRP/DIDP/ FDDA/OMPT/CDER/GRP/DIDP/ FDDA/OMPT/CDER/GRP/DIDP/ FDDA/OMPT/CDER/GRP/DIDP/ OC/OCC/	RYAN LYNCH POLICY AND REGULATORY REPORT - FT GROUP	CORR BETWEEN FDA AND DOJ RE PHARMACEUTICALS IN CHINA
2013-5801	07/25/2013 08/22/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Scott Panagiotis Scott Panagiotis	LLOYD, INC, SHENANDOANH, IA - 483 04/16/2013
2013-5802	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDDA/OMPT/CDER/GRP/DIDP/ FDDA/OMPT/CDER/GRP/DIDP/ FDDA/OMPT/CDER/GRP/DIDP/	Paul Greenberg Analysis Group, Inc.	FDA SURVEILLANCE OF ADVERSE DRUG EFFECTS BY B. TIMOTHY HUMMER
2013-5803	07/25/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Laura Strickler	RANBAXY - PICTURES, IMAGES, VIDEOS OF FACILITIES TAKEN DURING INSPECTIONS OR RAIDS (01/01/2007 -

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	08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	CBS NEWS	01/01/2013)
2013-5804	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MAHYAR ETMINAN PHARM D BC CHILDRENS HOSPITAL AND BC WOMENS HOSPITAL & HEALTH CENTRE	CIPROFLOXACIN, LEVOFLOXACIN, MOXIFLOXACIN - AER 1990 TO PRESENT
2013-5805	07/25/2013 08/22/2013	FDA/OMPT/CTP/OD/	NATALIE N. SANDERS LATHAM & WATKINS LLP	NEWPORT - NON MENTHOL GOLD BOX 100 STN SE0003730, EA; NEWPORT - NON MENTHOL GOLD BOX STN SE0003731, EA
2013-5806	07/25/2013 08/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	BRETT PARK CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-5807	07/25/2013 08/22/2013	FDA/OF/CFSAN/OCD/EOS/	FATIMA ASLAM Keller and Heckman LLP	FAP 3A4798
2013-5808	07/25/2013 08/22/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARLA SCARMAZZI King & Spalding LLP	DKT 2007D-0369; CYCLOSPORINE OPHTHALMIC EMULSION CORR, BIOAVAIL, BIOEQV TESTING, ETC
2013-5809	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MOTT, VIRGINIA LEE	TEVA PHARMACEUTICALS - NAPROXEN AER
2013-5810	07/25/2013 08/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	ZACHARY K. GIAMPA, Esq LAW OFFICE OF RICHARD L GIAMPA	INDIVIDUAL RECS
2013-5811	07/25/2013 08/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARYANNE PLAYER CSL BEHRING	THROMBATE III (ANTITHROMBIN III) SBA

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		FDA/OMPT/CBER/OCOD/DDOM/ALFB/		
2013-5812	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K102469
2013-5813	07/26/2013 08/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Kimberly Ha BIOPHARM INSIGHT	TECFIDERA - MEDWATCH REPORTS
2013-5814	07/26/2013 08/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	Steven R. Reed LANSING STATE JOURNAL	RECALL B-1675-12
2013-5815	07/26/2013 08/23/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - EIR 2002
2013-5816	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Becky Ditty Stryker IMT	K050973
2013-5817	07/26/2013 08/23/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	Rachel Johnson FOI Services, Inc.	ALLERGAN, IRVINE, CA - 483, EIR
2013-5818	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4072
2013-5819	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2011-9324
2013-5820	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2012-566
2013-5821	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4874
2013-5822	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3586
2013-5823	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2009-1512
2013-5824	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2008-8317
2013-5825	07/26/2013	FDA/OC/OES/DFOI/	Rachel Johnson	2004-25710

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	08/23/2013		FOI Services, Inc.	
2013-5826	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2004-25710
2013-5827	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2004-15710
2013-5828	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2008-6750
2013-5829	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2012-7961
2013-5830	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4306 - REQUEST LETTER ONLY
2013-5831	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 125433
2013-5832	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Greenberg Analysis Group, Inc.	FDA INVESTIGATING REPORTS OF POSSIBLE INCREASED RISK OF PANCREATITIS AND PRE-CANCEROUS FINDINGS OF THE PANCREAS FROM INCRETIN MIMETIC DRUGS FOR TYPE 2 DIABETES - MATERIALS SUBMITTED BY PETER BUTLER
2013-5833	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Benjamin Fleischman Decade Capital Management LLC	FDA HOSPITAL SURVEY, MEDSUN REPORT RE INTUITIVE SURGICAL
2013-5834	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4719 - REQUEST LETTER ONLY
2013-5835	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4570 - REQUEST LETTER
2013-5836	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4568 - REQUEST LETTER
2013-5837	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2011-8979
2013-5838	07/26/2013 08/23/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Jane Bentley Alcon Laboratories, Inc.	ALCON LABS, HOUSTON, TX - EIR 05/13/2013 - 07/19/2013
2013-5839	07/26/2013	FDA/OGROP/ORA/PA-FO/LOS-	Jane Bentley	ALCON LABS, IRVINE, CA - EIR 07/01/2013 - 07/19/2013

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	08/23/2013	DO/LOS-CB/	ALCON LABORATORIES	
2013-5840	07/26/2013 08/23/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4480 - REQUEST LETTER
2013-5841	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOYCE MARSH HOLMES WEDDLE & BARCOTT	PRODISC-1 TOTAL DISC REPLACEMENT P050010 - AMENDMENTS, POST-MARKET STUDIES, MDRS, ETC 8/14/11
2013-5842	07/26/2013 08/23/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRAD SCHONHOFT	SAREPTA THERAPEUTICS, BOTHELL, WA - POTENTIAL SURROGATE ENDPOINTS MINS, EIRS, DISCUSSIONS 9/20/12 TO 7/24/13
2013-5843	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KATHRYN A PRYOR SIMON GREENSTONE ET AL	MOTRIN, ADVIL, ETC - AERS
2013-5844	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PRENDERGAST, JOYCE E	CHANTIX (VERENICLINE) - AERS 3/1/13-7/18/13
2013-5845	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	CHILDREN'S ADVIL SUSPENSION LIQUID ALL FLAVORS - AERS1969 TO 2013
2013-5846	07/26/2013 08/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CUCHETTI, RON	SHELF LIFE EXTENSION PROGRAM (SLEP) - DRUGS TESTED, STORAGE CONDITONS PRIOR TO TESTING, LENGTH OF TIME IN STORAGE, ETC
2013-5847	07/26/2013 08/23/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	JILLIAN NASH ALLTECH INC	RIDLEY FEED INGREDIENTS, MEDNODOTA, IL - 483S PAST 10 YRS
2013-5848	07/26/2013 08/23/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ CVM/OC/	SHARON MOZZI HANOVER INSURANCE GROUP	PETRA PET INC - BEEFEATER SWEET POTATO SNACKS TEST RESULTS

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2013-5849	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachael Tanner Rachael Tanner	K030136, K080704
2013-5850	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kaori Asakawa EXPERIEN GROUP LLC	K052840
2013-5851	07/26/2013 08/23/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	NANDINI GOPINADH ALLIANCE FOR NATURAL HEALTH USA	DIETARY SUPPL - AERS, ENFORCEMENT ACTIONS 1/1/08 TO 12/21/12
2013-5852	07/26/2013 08/23/2013	CVM/OCD/	KRISTI O SMEDLEY Center for Regulatory Services, Inc.	NOVOZYMES - GENETICALLY MODIFIED YEAST FOR USE IN ETHANOL PRODS - SUMISSIONS, COMM
2013-5853	07/26/2013 08/23/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	PARKER, RENEE C	BORDEN CHESSE - CMPLNT #132973
2013-5854	07/26/2013 08/23/2013	FDA/OC/OES/DDM/	ERIN HUGHES ERIN HUGHES	DKT FDA-2013-P-0148
2013-5855	07/26/2013 08/23/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2007-D-0369, 1998D-0388
2013-5856	07/26/2013 08/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lauren A. Farruggia Hyman, Phelps & McNamara	P890003 S254
2013-5857	07/26/2013 08/23/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	Karen Marshall Tarsa Therapeutics, Inc.	PHARMACEUTICALS INTERNATIONAL INC - 482, 483, RESPONSES ETC (01/26/2011 - 07/26/2013)
2013-5858	07/26/2013 08/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Michelle Elizabeth Legiec Eagle Pharmaceuticals, Inc.	CIPLA LIMITED, INDIA - EIR, ANDA 200540 (04/01/2013 - 07/01/2013) /01/2013 - 7/01/2013)
2013-5859	07/26/2013 08/23/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/ FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	TOBACCO MANUFACTURERS - 483, EIR 7/1/12 TO 6/30/13

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		FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/		
2013-5860	07/29/2013 08/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FHA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jonathan J. Darrow HARVARD MEDICAL SCHOOL DEACONESS HOSPITAL	SMG 4820.3 - 1992, 2013
2013-5861	07/29/2013 08/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Diana Lac Genentech	CMX001 - FAST TRACK APPLICATION AND CORRESPONDENCE
2013-5862	07/29/2013 08/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	VAERS 494348
2013-5863	07/29/2013 08/26/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Barbara Kowinsky KOWINSKY, BARBARA	BOCCHE LABORATORIES, SANTA CLARITA, CA - EIR (01/01/2012 - 07/25/2013)
2013-5864	07/29/2013 08/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas C. Stover Swiftwater Group LLC	TORECAN - PRESCRIBING INFORMATION, SBA REVIEWS
2013-5865	07/29/2013 08/26/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	Rachel Johnson FOI Services, Inc.	LIFESCAN, AGUADILLA, PR - EIR, 483
2013-5866	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO MARKET ORDERS
2013-5867	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Albert Lee AGILENT TECHNOLOGIES	ROCHE, AFFYMETRIX AMPLICHIP CYP450 - APPLICATION
2013-5868	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Grace Bartoo Decus Biomedical	K120282
2013-5869	07/29/2013 08/26/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Rachel Johnson FOI Services, Inc.	LIFESCAN, MILPITAS, CA - EIR, 483
2013-5870	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	Yitzchak Jacoboviz Capstone Law APC	CTP CORR WITH OMB RE MENTHOL CIGARETTES; : 03/31/2011 - 07/26/2013; RECORDS OF MEETINGS OR CALLS WITH OMB AND CTP RE MENTHOL CIGARETTES; RECS RE

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				MENTHOL CIGARETTES AND OMB ETC
2013-5871	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	LIFESCAN, IVERNESS, UK - EIR, 483
2013-5872	07/29/2013 08/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Mara Jes Sanz CHEMO GROUP	NDA 021162 - AVAILABILITY OF RECORDS TO PUBLIC
2013-5873	07/29/2013 08/26/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Tonya White-Salters White-Salters Consulting, LLC	BIORELIANCE, ROCKVILLE, MD - EIR, 483 (01/01/2010 - 06/20/2013)
2013-5874	07/29/2013 08/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OC/OES/DFOI/	Lynn T. Shepler, MD JD LTS & Associates /LYNN SHEPLER, MD JD	BAXTER - FORM 1571, 1572
2013-5875	07/29/2013 08/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Robin M Berger, MD Robin Berger MD PC	ISOTRETINOIN - EFFICACY OF IPLEDGE PROGRAM
2013-5876	07/29/2013 08/26/2013	FDA/OGROP/ORA/ORO/DIOP/ FDA/OMPT/CDRH/OCER/DFOI/	Kenneth Tice Accogent LLC	COMMUNICATION AND POWER INDUSTRIES - IMPORTER IDENTIFICATION, DELISTING
2013-5877	07/29/2013 08/26/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Christine Rosenbaum Rosenbaum, Christine	SAMPLE RESULTS
2013-5878	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	BTran Tran Associates	K093585, K963228
2013-5879	07/29/2013 08/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	P880047
2013-5880	07/29/2013 08/26/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 7/22/2013 - 7/26/2013
2013-5881	07/29/2013 08/26/2013	FDA/OF/CFSAN/OCD/EOS/	KRISTI O. SMEDLEY, Ph.D. Center for Regulatory Services, Inc.	FAP 6A3903
2013-5882	07/29/2013 08/26/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	ANGIODYNAMICS - 483 RESP 9/24/12

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2013-5883	07/29/2013 08/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA LIGORSKY CARROLL KELLY ET AL	IMPLANON - AER
2013-5884	07/29/2013 08/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JEROME P. PRATHER GARMER & PRATHER PLLC	MERCK & CO - VIOXX
2013-5885	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	ANNE D. SPIGGLE Patton Boggs LLP	NEWPORT MENTHOL GOLD BOX - STN SE0003731 EQUIV
2013-5886	07/29/2013 08/26/2013	FDA/OMPT/CTP/OD/	ANNE D. SPIGGLE Patton Boggs LLP	NEWPORT NON MENTHOL GOLD BOX 100 - STN SE0003730 EQUIV
2013-5887	07/29/2013 08/26/2013	FDA/OC/OES/DDM/	MICHELLE MORIN COVINGTON & BURLING LLP	CITIZEN PETITION OF DR J BARTHELOW CLASSEN 6/26/03 TO 8/5/02
2013-5888	07/29/2013 08/26/2013	FDA/OF/CFSAN/OCD/EOS/	JOAN SYLVAM BAUGHAN Keller and Heckman LLP	FCN 1231
2013-5889	07/30/2013 08/27/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Christina Wolff Otsuka America Pharmaceutical Inc.	ARIFULLA KHAN, MD - EIR, 483, CLOSE OUT LETTER (01/30/2012 - 03/28/2012)
2013-5890	07/30/2013 08/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 50795 S 2, 10
2013-5891	07/30/2013 08/27/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	Theodore Maya Ahdoot & Wolfson, PC	REFERRALS, REQUESTS FOR GUIDANCE FROM US DISTRICT COURTS RE LABELING OF FOOD PRODUCTS LAST TEN YEARS
2013-5892	07/30/2013 08/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Linenberger, MD Michael Linenberger	FILGRASTIM - AERS
2013-5893	07/30/2013 08/27/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Lajoya Sanfor/Jackson Sanford/Thomas, LaJoya	INDIVIDUAL RECS

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2013-5894	07/30/2013 08/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Priya Jambhekar Alliqua Inc	K040019
2013-5895	07/30/2013 08/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHEA N SHAVER REILLY POZNER LLP	PROZAC (FLUOXETINE HCL) NDA 18-936, NDA 20-974 - AERS, MOR, APRVL LTRS, LBLG 12/29/87 TO 7/6/00, ETC
2013-5896	07/30/2013 08/27/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	DAMARYS DE CASTILLO GOYA DE PUERTO RICO INC	OVAL SARNDIES ENTRY #BXH-0006701-2; GROUND GREEN PEPPERS BXH-0006963-8/1/2, BXH-0006946-3/1/2 - RECS
2013-5897	07/30/2013 08/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	ZARAH LEVIN-FRAGASS ESQ LANIER LAW FIRM	DR PETER S FINAMORE, WINTHROP UNIV HSOPTIAL, BOSTON SCIENTIFIC CORP - TRANSVAGINAL SURGICAL MESH CMLPTS, MDRS, CORR, ETC
2013-5898	07/30/2013 08/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Christina Wolff Otsuka America Pharmaceutical Inc.	AHMAD HATIM SULAIMAN - EIR, 483, CLOSE OUT LETTER (04/09/2012 - 04/13/2012)
2013-5899	07/30/2013 08/27/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Joan Stitt (UG2CD-16); phone 267-305-7723 MERCK & CO., INC.	MERCK AND CO, WEST POINT, PA - INSPECTOR NOTES (01/15/2013 - 02/06/2013)
2013-5900	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/15-19/13
2013-5901	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/8-12/13
2013-5902	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 7/8-12/13
2013-5903	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 7/15-19/13
2013-5904	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/8-12/13
2013-5905	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	DEBI L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/15-19/13
2013-5906	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 7/15-19/13

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2013-5907	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	DEBI L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/8-12/13
2013-5908	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/8-12/13
2013-5909	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/15-19/13
2013-5910	07/30/2013 08/27/2013	ORA/ ORA/	Doe J	MAIN STREET FAMILY PHARMACY, BLACK CENTER - METHYLPREDNISOLONE ACETATE (MPA) TEST RESULT, INVESTIGATION, PI, ETC
2013-5911	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/15-19/13
2013-5912	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 7/8-12/13
2013-5913	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/15-19/13
2013-5914	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/8-12/13
2013-5915	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/15-19/13
2013-5916	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/8-12/13
2013-5917	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 7/15-19/13
2013-5918	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	CLOSED DAILY LOG 7/15-19/13
2013-5919	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/15-19/13
2013-5920	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/8-12/13
2013-5921	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/8-12/13
2013-5922	07/30/2013	FDA/OC/OES/DFOI/		DAILY CLOSED LOG 7/15-19/13

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	08/27/2013		FOI Services, Inc.	
2013-5923	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/15-19/13
2013-5924	07/30/2013 08/27/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/8-12/13
2013-5925	07/31/2013 08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	LUBOCK, PAUL	K111705
2013-5926	07/31/2013 08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	MATT CLAUSEN MEDLINE INDUSTRIES INC	CHESTER PACKAGING LLC K841871
2013-5927	07/31/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CHLOE BOWER SYN GEN	CYTOMEDIX INC - ANGEL CONCENTRATED PLATELET RICH PLASMA BK110046
2013-5928	07/31/2013 08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	JOYCE MARSH HOLMES WEDDLE & BARCOTT	PRODISC 1 TOTAL DISC REPLACEMENT - AER, PMA STUDY
2013-5929	07/31/2013 08/28/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	PETER A. QUINTER GRAY ROBINSON ATTY	ENTRY NO JN8-00208975
2013-5930	07/31/2013 09/03/2013	FDA/OO/OHR/	ALEXIS N. TSOTAKOS, Esq. THE LAW OFFICES OF GARY M GILBERT & ASSOCIATES PC	INDIVIDUAL RECS
2013-5931	07/31/2013 08/28/2013	FDA/OC/OES/DFOI/	PATRICK A. ELWARD BINGHAM GREENBAUM ET AL	BAUSCH & LOMB INC - 2006 FUSARIUM KERATITIS OUTBREAK
2013-5932	07/31/2013 10/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KYLE ROCKERSHOUSEN WALSH KNIPPEN ET AL	VERSCD (MIDAZOLAM) PCKG
2013-5933	07/31/2013 08/28/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	KRISTEN S. MOYERS WRIGHT LINDSEY & JENNINGS	KIMBERLY CLARK - KOTEX NEW BALANCE SECURITY TAMPON RECALL
2013-5934	07/31/2013 08/28/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MICHELLE L. MORIN COVINGTON & BURLING LLP	VACCINES & DIABETES MTG W/DR BART CLASSEN 1/30/95

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2013-5935	07/31/2013 08/28/2013	CVM/OCD/ FDA/OC/OES/ OC/OCC/	HANNAH CONNOR Humane Society of the United States	RACTOPAMINE - APRVL
2013-5936	07/31/2013 08/28/2013	FDA/OO/OFBA/OAGS/	NIKA GRACI PLANNED PARENTHOOD	SITE VISITS REVIEWS CONDUCTED AT OFFICE OF POPULATION AFFAIRS 2010, 2011, 2012
2013-5937	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/	Robert Blinn Pura Vida Funds	ST JUDE MEDICAL - 483 (08/01/2012 - 07/29/2013)
2013-5938	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Angela Fu UNIVERSITY OF MARYLAND	K032986, K061079, K070211
2013-5939	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Karen L. Richards Singulex, Inc.	K093758
2013-5940	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Reza Davani Janet Jenner & Suggs LLC	K080238 K082052 K091057 ETC
2013-5941	08/01/2013 08/29/2013	FDA/OC/OES/DDM/	John Pribble The Medicines Company	DKT. 98-P-0086/CP1
2013-5942	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mike O'Hara EPC	K123731
2013-5943	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen L. Richards Singulex, Inc.	K111452
2013-5944	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sean Higgins ANDREWS & THORNTON	ANDA 202077
2013-5945	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Namsavanh IntelGenx Corp.	NDA 017525
2013-5946	08/01/2013 08/29/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Joan Stitt (UG2CD-16); Phone - 267-305-7723 MERCK & CO., INC.	MERCK AND CO, DURHAM, NC - INVESTIGATOR NOTES (08/20/2012 - 08/31/2012)
2013-5947	08/01/2013 08/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mark Little Mark Little	COMMERCIAL IND SUBMISSIONS

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2013-5948	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E Faerber Dartmouth Inst. Cent. For Med. Media.	NDA 022083 S 16
2013-5949	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	F William Danby Danby and Margesson Dermatology	NIZORAL, SPORANOX - AERS
2013-5950	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Becky Ditty Stryker IMT	K111642
2013-5951	08/01/2013 08/29/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Susan Zolnier Zolnier, Susan	CHARLES RIVER CLINICAL SERVICES, TACOMA, WA - EIR, 483 (01/01/2010 - 12/31/2011)
2013-5952	08/01/2013 08/29/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	William B Smith, MD New Orleans Center for Clinical Research	NEW ORLEANS CENTER FOR CLINICAL RESEARCH - EIR (09/01/1988 - 09/30/1988)
2013-5953	08/01/2013 08/29/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Lori Hays Merz North America, Inc.	MERZ AESTHETICS, FRANKSVILLE, WI - EIR (3/12/2013 - 04/19/2013)
2013-5954	08/01/2013 08/29/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Phil Boehm Bimbo Bakeries USA	BIMBO BAKERIES, DENVER, CO - EIR 2/12/13
2013-5955	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sean Higgins ANDREWS & THORNTON	ANDA 201786
2013-5956	08/01/2013 08/29/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	ORR, PATRICK	VITEK INC - IMPLANT RECS, CORR
2013-5957	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/	BLAZE, D'LANIE	MONITORING INCOMING SEAFOOD FROM JAPAN FOR RADIOACTIVITY - RECS
2013-5958	08/01/2013 08/29/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/ATL-	DENNIS L WEBB WEBB & SCARMOZZINO ATTY	GOLDCOAST SALADS - BLUE CRAB SPREAD CONTAMINATION INVESTIGATION 1/13

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		DO/ATL-CB/		
2013-5959	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TIMOTHY M O'BRIEN LEVIN PAPANTONIO THOMAS ET AL	MERCK - FOSAMAX NDA 20-560 CMLPTS, RPTS, CORR, ETC
2013-5960	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JACKIE HERNDON ZAREMBA BROWNELL & BROWN PLLC	ARAVA (LEFLUNOMIDE) - RECS (CERTIFIED)
2013-5961	08/01/2013 08/29/2013	FDA/OC/OES/DDM/	BRIAN BOXER WACHLER BOXER WACHLER VISION INSTITUTE	OPHTHALMIC DVCS PANEL MTG - TRANS 1995 & 1996
2013-5962	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	EUROFINS LANCASTER LAB, WATERFORD, IRELAND - 483 3/13
2013-5963	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Christina Wolff OTSUKA AMERICA PHARMACEUTICAL INC	MARK LERMAN - EIR, 483, CLOSE OUT (02/27/2012 - 04/04/2012)
2013-5964	08/01/2013 08/29/2013	FDA/OF/CFSAN/OCD/EOS/	A. Philip Leber A Philip Leber Consulting	FCN 176
2013-5965	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Margaret Sestrom PFIZER	MEDROL - CMC REVIEW
2013-5966	08/01/2013 08/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robin Richardson Robin Richardson	CELSTONE SOLUSPAN INJECTIONI - AERS, INSERT
2013-5967	08/01/2013 08/29/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	David M. Pike David M. Pike	LIQUID PACKAGING RESOURCES, INC, ATLANTA, GA - PLANT REVIEW AUDIT INFORMATION (01/01/2008 - 12/31/2009)
2013-5968	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Pamela Heitz, Medtronic Neuro Regulatory Operations Medtronic Neuromodulation	13TH SYNCHROMED ANNUAL REPORT FOR 03/14/2000 TO 03/13/2001; P860004/R022

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2013-5969	08/01/2013 10/28/2013	FDA/OF/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT - AERS (08/01/2010 - 12/31/2010)
2013-5970	08/01/2013 08/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	EUROFINS LANCASTER LAB, WATERFORD, IRELAND - EIR 3/13
2013-5971	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHIRLEY ROBERSON OMRON HEALTHCARE INC	LECHNOLOGIES RESEARCH INC - ELECTROCARDIOGRAPH K052767
2013-5972	08/01/2013 08/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHIRLEY ROBERSON OMRON HEALTHCARE INC	MICROLIFE - BLOOD PRESSURE MONITOR K013485, K080337, K073198, ETC
2013-5973	08/01/2013 08/29/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	Francis, Ana M	2012-5775
2013-5974	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16); 267-305-7723 MERCK & CO., INC.	CLOSED FOIA REQUESTS 7/1-31/2013
2013-5975	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16); 267-305-7723 MERCK & CO., INC.	FOI DAILY LOG 7/1-31/2013
2013-5976	08/02/2013 08/30/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	Kellie M. Collins Golden and Walters	LANHAM CATTLE FARM, MIDDLESBURG, KY - INVESTIGATION RECS (12/17/2012 - 07/31/2014)
2013-5977	08/02/2013 08/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Stacy Woeppel B. Braun Medical Inc.	NDA 019627 S060
2013-5978	08/02/2013 08/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Richard Gross Gross, Richard E	K090169
2013-5979	08/02/2013 08/30/2013	FDA/OF/CFSAN/OCD/EOS/	Jorge Flores P.A Alberto Soler	GRAS DETERMINATION OF COCA LEAF (DECOCAINIZED)
2013-5980	08/02/2013 08/30/2013	FDA/OF/CFSAN/OCD/EOS/	Jorge Flores P.A Alberto Soler	FEMA 2329/CAS: 977073-62-3/EINECS: 283-877-4/21 - DATE OF APPROVAL
2013-5981	08/02/2013 08/30/2013	FDA/OF/CFSAN/OCD/EOS/	Jorge Flores P.A Alberto Soler	1958 GRAS LIST EXEMPT SUBSTANCE
2013-5982	08/02/2013	FDA/OGROP/ORANE-FO/NYK-	Gary Waugaman	NEW YORK STATE E COLI SPINACH AND SPRING MIX

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	08/30/2013	DO/NYK-DCB/	Lakeside Organic Gardens LLC	OUTBREAK - INVESTIGATION REPORT 10/01/2012 - 12/31/2012
2013-5983	08/02/2013 08/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sandra Witt sandra witt	KNEE REPLACEMENT ADVERSE EVENTS
2013-5984	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bonnie Williams FOI Services, Inc.	ANDA 202631
2013-5985	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bonnie Williams FOI Services, Inc.	ANDA 201951
2013-5986	08/02/2013 08/30/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Paul Knoepfler Paul Knoepfler/UC Davis School of Medicine	CELLTEX - REPORTS, CORR, INVESTIGATIONS (01/01/2013 - 12/31/2013)
2013-5987	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vidhu Thaker Boston Childrens Hospital	ACUTANE - AERS
2013-5988	08/02/2013 08/30/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Rao Maddula ARIAD PHARMACEUTICALS INC	AMPAC FINE CHEMICALS - 483, EIR (10/01/2009 - 10/04/2010)
2013-5989	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sue Corbett THE RESEARCH INVESTMENT, INC.	PERIOD SAFETY UPDATE REPORT EPOS 12, SOLID 1000185514
2013-5990	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	CAMPTOSAR - AERS
2013-5991	08/02/2013 08/30/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	Michele Aguirre Clinical Research Advantage	JOHN F SPEER, ARLINGTON, TX - INSPECTION RECS (01/01/1986 - 12/30/1986)
2013-5992	08/02/2013	FDA/OMPT/CDER/GRP/DIDP/	Anne Madej	NDA 202088

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	08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Genentech	
2013-5993	08/02/2013 08/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K RELEASED UNDER FOIA JULY 2013
2013-5994	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lucie Begert GUERBET LLC	MALLINCKRODT SODIUM CHLORIDE INJECTION 0.9% MODULE 5 CLINICAL, MODULE 2.5 CLINICAL OVERVIEW, MODULE 2.7 CLINICAL SUMMARY
2013-5995	08/02/2013 08/30/2013	FDA/OF/CFSAN/OCD/EOS/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	DIETARY SUPPLEMENT AERS (09/01/2012 - 06/30/2013)
2013-5996	08/02/2013 09/26/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Surgery Center of the Rockies Boulter, Suzanne	SURGICAL TISSUE NETWORK, MUSCULOSKELETAL TRANSPLANT FOUNDATION, DOROTEA, ETC - AERS, INSPECTIONS (01/01/2012 - 07/31/2013)
2013-5997	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	COMPUTER USAGE FROM 7/1/10 TO 12/31/10
2013-5998	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	MOTEN, LAVEETA D	COMPUTER USAGE FROM 1/1/11 TO 7/14/11
2013-5999	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	MOTEN, LaVEETA D	COMPUTER USAGE FROM 12/5/11 TO 6/30/12
2013-6000	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M. GARTZ ELI LILLY & CO	SHAANXI HANJIANG PHARMACEUTICAL GROUP CO, LTD, HANZHONG, CHINA - EIR 11/21/08, 10/14/10
2013-6001	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	VIOXX - FAERS 1969 TO 2013

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6002	08/02/2013 08/30/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDA NEWS	ALL 483 NOTICES RECIEVED FOR FACILITIES 7/13
2013-6003	08/02/2013 08/30/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-5582
2013-6004	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREA L. SCHROEPFER WALL STREET JOURNAL	SPECTRUM PHARMACEUTICALS - BELINOSTAT NDA
2013-6005	08/02/2013 08/30/2013	FDA/OC/OES/	HOFFMAN, DAVID .	RISE OF ANTIMICROBIAL RESISTANCE AS A PUBLIC POLICY PROBLEM SINCE 1/09
2013-6006	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	ALLERGAN INC NDA PK200301 1/03 TO 5/13
2013-6007	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	SERENITY PHARMACEUTICALS LLC NDA PK200301 1/03 TO 5/13
2013-6008	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	SERENITY PHARMACEUTICALS LLC NDA PK200301 1/03 TO 5/13
2013-6009	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	ALLERGAN INC NDA PK200301 1/03 TO 5/13
2013-6010	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	CFN PHARMA LLC NDA PK200301 1/03 TO 5/13
2013-6011	08/02/2013 08/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	CNF PHARMA LLC NDA PK200301 1/03 TO 5/13

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2013-6012	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA YEAGER KSHB-TV	ESSURE - MTG MINS , CORR, PMA APRVL 1/1/96 TO 7/31/13
2013-6013	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA YEAGER KSHB-TV	AVAILMED SA DE CV, TIJUANA, MEXICO - EIRS, WARNING LTRS 1/1/00 TO 7/31/13
2013-6014	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JULIA P DURAN GOODWIN PROCTER LLP	INJECTAFER (FERRIC CARBOXYMALTOSE INJ) - NDA 203-565 - SBA
2013-6015	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN E NIZNIK PORZIO BROMBERG & NEWMAN PC	INJECTAFER (FERRIC CARBOXYMALTOSE INJ) - NDA 203-565 - SBA
2013-6016	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS US LLP	INJECTAFER (FERRIC CARBOXYMALTOSE) NDA 203-565 - SBA
2013-6017	08/05/2013 09/03/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	JOSH SULTAN CBS 2 NEWS CHICAGO	VERMMA, SCOTTSDALE, AZ - EIRS, CO RESP 10/1/12 TO 1/1/13
2013-6018	08/05/2013 09/03/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	TRAVIS SCHAFTENAAR MANULIFE ASSET MANAGEMENT	ANGIODYNAMICS - 483S 9/24/12
2013-6019	08/05/2013 09/03/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	BOBBIE J COLES-BROWN CARACO PHARMACEUTICAL LABS LTD	SUN PHARMACEUTICAL INDUSTRIES INC - ACKNOWLEDGEMENT RECEIPT LTR 7/21/11
2013-6020	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	EDWARD B GERARD ROBBINS ARROYO LLP	STAR SCIENTIFIC INC - DEVELOPMENT, PROMOTIONS, SALES
2013-6021	08/05/2013 09/27/2013	FDA/OF/CFSAN/OCD/EOS/	LI ZHANG BASF Corp.	OMNOVA SOLUTIONS INC - FCN 244
2013-6022	08/05/2013 09/03/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	WILLIAM DOFFERMYRE WILLIAMS & CONNOLLY LLP	BEEF PRODUCTS INC - LEAN FINELY TEXTURED BEEF, FAT REDUCED BEEF, BONELESS LEAN BEEF TRIMMINGS CORR BETWEEN BPI EMPLOYEES, OLSSON FRANK & WEEDA PC, CMLPTS, ETC
2013-6023	08/05/2013	CVM/OCD/	Finola McConaghy	NADA 131-310

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	09/03/2013		Ceva Animal Health	
2013-6024	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma, Inc.	ADDERRAL XR CAPSULE 5, 10, 15, 20, 25, 30 MG
2013-6025	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee TRIS PHARMA INC	ADDERRALL IR TABLETS 5, 7.5, 10, 12.5, 15, 20, 30 MG
2013-6026	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bonnie Williams FOI Services, Inc.	ANDA 202542
2013-6027	08/05/2013 09/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Adrienne E. Faerber, PhD Dartmouth Inst. Cent. For Med. Media.	NDA 203188 - UNREDACTED MEDICAL AND STATISTICAL REVIEW
2013-6028	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jack Rogers Polymer Technology Systems, Inc.	K090405, K130295
2013-6029	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	Stanton A. Glantz, PhD UNIVERSITY OF CALIFORNIA SAN FRANCISCO	STN SE0003730
2013-6030	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	Stanton A. Glantz, PhD UNIVERSITY OF CALIFORNIA SAN FRANCISCO	STN SE0003731
2013-6031	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty M Johnson Technolas Perfect Vision GmbH	K102727
2013-6032	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Betty M Johnson Technolas Perfect Vision GmbH	K113479
2013-6033	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thambiah Sundaram Sundaram, Thambiah	K050591, K032914, K971432 ETC
2013-6034	08/05/2013 09/03/2013	FDA/OMPT/CTP/OD/	Allison O'Donnell Campaign for Tobacco Free Kids	NEWPORT NON-MENTHOL GOLD BOX 100, NEWPORT NON-MENTHOL GOLD BOX - FDA PREPARED RECS RE DESIGNATION AS SUBSTANTIALLY EQUIVALENT TO GRANDFATHERED PREDICATE PRODUCTS

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2013-6035	08/05/2013 09/03/2013	FDA/OC/OES/DDM/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/ OC/OL/	Patrick Terpstra Cox Media Group	COMMENTS TO FDA RE POLICY BANNING BLOOD 01/13/2013 - 08/02/2013
2013-6036	08/05/2013 09/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jose Schwank Starq	K950621
2013-6037	08/05/2013 09/03/2013	FDA/OGROP/ORR/PA-FO/SAN- DO/SAN-CB/	David Dick UNIVERSITY OF IOWA	MOLECULAR IMAGING PROGRAM, STANFORD, CA - EIR (06/01/2007 - 12/12/2011)
2013-6038	08/05/2013 09/03/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Craig Miles CR MILES, PC	APPROVED PHASE I TRIAL FOR TREATMENT OF HYPERTROPHIC SCAR DEFECT
2013-6039	08/05/2013 09/03/2013	FDA/OGROP/ORR/SW-FO/DAL- DO/DAL-CB/	Sandy O'Kelley Merial Limited	NU-ERA FARMS, STILLWATER, OK - EIR 12/21/2012 - 02/28/2013
2013-6040	08/06/2013 09/04/2013	FDA/OF/CFSAN/OCDE/EOS/	JONATHAN W EMORD EMORD & ASSOCIATES, P.C.	BRASSICA PROTECTION PRODUCTS - GLUCORAPHANIN IN BEVERAGES, GRAS NOTIFICATION
2013-6041	08/06/2013 09/04/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCDE/EOS/	ANGELA SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	HYDROXYCUT, SMARTBURN, CREATINE 6000, ETC - CAERS 5/13 TO PRESENT
2013-6042	08/06/2013 09/04/2013	FDA/OGROP/ORR/NE-FO/NYK- DO/NYK-DCB/	K MICHELLE VASSALLO LINCARE INC	ANTHEM HEALTH SERVICES INC, NY - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-6043	08/06/2013 09/04/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	EMILY K STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	US PHARMACOPEIA CONVENTION, NATIONAL FORMULARY (USP-NF) - ELEMENTAL IMPURITIES STANDARDS, CORR
2013-6044	08/06/2013 09/04/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	EMILY K STRUNK AKIN GUMP STRAUSS HAUER & FELD, LLP	US PHARMACOPEIA, NATIONAL FORMULARY (USP-NF) - CORR, MEMORANDA OF UNDERSTANDING (MOU), EI STANDARDS, ETC
2013-6045	08/06/2013 09/04/2013	FDA/OMPT/CDER/ORD/DIDP/ FDA/OMPT/CDER/ORD/DIDP/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	PEDICULICIDES - CORR, LACK OF EFFICACY RECS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6046	08/06/2013 09/04/2013	FDA/OC/OES/DDM/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	DKT 2010P-0312
2013-6047	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - LITE PELVIC FLOOR REPAIR KIT K103426
2013-6048	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	AARON L EMBREY ANDRUS HOOD & WAGSTAFF PC	BOSTON SCIENTIFIC CORP - PINNACLE LITE PELVIC FLOOR REPAIR KIT, POSTERIOR UPHOLD LITE K122459
2013-6049	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK - PEDIATRIC/CHILD FACEMASK K113340
2013-6050	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	KIMBERLY-CLARK - PEDIATRIC/CHILD FACEMASK K103150
2013-6051	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sarah Biwer DHL Global Forwarding	DRUG ESTABLISHMENT LIST 01/01/2013 - 12/31/2013
2013-6052	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrea McKeever South University School of Pharmacy	CABERGOLINE THERAPY - AERS
2013-6053	08/06/2013 09/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Patrick J. Higgins Powers & Santola, LLP	KARL STORZ GMBH & CO ETC - REGISTRATIONS, 510K NOTIFICATIONS, MEDICAL DEVICE LISTINGS ETC
2013-6054	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ed Dougherty Dougherty Modin Holloway & Kardis	ISONIAZID - BOX WARNING, PACKAGE INSERTS, PRECAUTIONS ETC
2013-6055	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lia Obata Dowd DOWD & DOWD PC	MIRENA - AERS, APPLICATIONS, WARNINGS ETC
2013-6056	08/06/2013 09/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Melanie Daub Melanie Daub	STRATTERA - FAERS

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6057	08/06/2013 09/04/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Joy flynn flynn, joy	SPECTRUM CHEMICAL AND LABORATORY PRODUCTS, NEW BRUNSWICK, NJ - EIR MOST RECENT
2013-6058	08/06/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	ASO4 - TESTING, SAFETY, APPROVAL FOR USE AS VACCINE ADJUVANT
2013-6059	08/06/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	AMORPHOUS ALUMINUM HYDROXYPHOSPHATE SULFATE - TESTING, SAFETY, APPROVAL AS VACCINE ADJUVANT
2013-6060	08/06/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Sarah Strand Sarah Strand - University of Arizona Department of Sociology	TESTING, SAFETY, APPROVAL OF THIMEROSAL/MERTHIOLATE
2013-6061	08/06/2013 09/04/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Linda Bowen SANOFI	JOST CHEMICAL COMPANY, BRECKENRIDGE HILLS, MO - EIR (05/01/2012 - 05/31/2012)
2013-6062	08/06/2013 09/04/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG (07/29/2013 - 08/02/2013)
2013-6063	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KRUSE, JANICE	SUROS SURGICAL SYSTEMS INC, INDIANAPOLIS, IN - ATEC BREAST BIOPSY SYS K042290
2013-6064	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRUSE, JANICE	RUBICOR MEDICAL INC, REDWOOD CITY, CA - MAGIC BREAST BIOPSY DVC K053151
2013-6065	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRUSE, JANICE	RUBICOR MEDICAL INC, REDWOOD CITY, CA - BREAST BIOPSY DVC K071048
2013-6066	08/07/2013 09/05/2013	FDA/OMPT/CDRH/OCER/DFOI/	JULIANNE SHERMAN CITIZENS COMMISSION ON HUMAN RIGHTS INTERNATIONAL	NEUROPSYCHIATRIC EEG BASED ASSESMENT AID (NEBA) SYS - ADHD NAMES, DISCLOSURE NOTICES, CLNCL STUDY 7/15/13
2013-6067	08/07/2013 09/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	AUGMENTIN SUSPENSION, AUGMENTIN-DUO SUSPENSION - FAERS 1969 TO 2013
2013-6068	08/07/2013 09/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	MEDWATCH RPTS CODED AS MEDICATION ERRORS 7/1-31/13
2013-6069	08/07/2013	FDA/OMPT/CDER/GRP/DIDP/		LITHIUM - AERS 2002 TO PRESENT

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	09/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RUSSELL #02B2141, DENNIS A	
2013-6070	08/07/2013 09/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOYCE E PRENDERGAST	CHANTIX (VERENICLINE) - ISRS 6554745, 6912111, 6977379, ETC
2013-6071	08/07/2013 09/05/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS Consulting Group, LLC	CSPC ZHONGNUO PHARMACEUTICAL (SHIJIAZHUANG) CO LTD, SHIJIAZHUANG, CHINA - EIRS 7/23-26/12
2013-6072	08/07/2013 09/05/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	CHASTITY RODRIGUEZ INTERNATIONAL SIGHT RESTORATION INC	LABORATORY CORPORATION OF AMERICA (LABCORP), TAMPA, FL - 483S, WARNING LTRS LAST 10 YRS
2013-6073	08/07/2013 09/05/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	BRENDAN J FLAHERTY PRITZKER OLSEN	TOWNSEND FARMS INC - ORGANIC ANTIOXIDANT BLEND HEPATITIS A OUTBREAK FOODBORNE PATHOGEN TESTING, EIRS, RPTS, ETC 2013
2013-6074	08/07/2013 09/05/2013	FDA/OC/OES/DFOI/	LAUREN S BARR JH BARR & ASSOCIATES LLC	2013-5606
2013-6075	08/07/2013 09/05/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-4749, 2013-4750
2013-6076	08/07/2013 09/05/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ED PETRUS Nobel Laboratories, LLS	LOG OF CDER FOIA REQUESTS PENDING
2013-6077	08/07/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARTIN RUBENSTEIN HOWARD M FILE ESQ PC	INDIVIDUAL RECS (CERTIFIED)
2013-6078	08/07/2013 09/05/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK CONWAY HOMER & CHIN-CAPLAN PC	INDIVIDUAL RECS (CERTIFIED)
2013-6079	08/08/2013	FDA/OMPT/CDER/GRP/DIDP/	Falgun K Shah	RANBAXY LABORATORIES, PUNJAB, INDIA - 483 (11/01/2012)

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	09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Reliance Mutual fund	- 03/01/2013)
2013-6080	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K013814 UNREDACTED
2013-6081	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K080383 UNREDACTED
2013-6082	08/08/2013 09/06/2013	FDA/OC/OES/DFOI/	Jason A Dean Hulsey Oliver & Mahar, LLP	2013-4772 CERTIFIED
2013-6083	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Stephen Dame DAME, STEPHEN	CELEXA - AERS
2013-6084	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeannie Lin Route One Investment Company	WOCKHARDT LIMITED, CHIKALTHANA, INDIA - 483 (07/15/2013 - 08/06/2013)
2013-6085	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K063271 UNREDACTED
2013-6086	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Richard Beasley Beasley, Richard	ALDARA - SIDE EFFECTS, DEATHS
2013-6087	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	claudia calla dentilab del peru	IUD TCU-380A - 1993 STUDY
2013-6088	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jessica Vickers Jessica Vickers	CITALOPRAM/QT PROLONGATION UPDATE - STUDIES USED
2013-6089	08/08/2013	FDA/OGROP/ORAC/CE-FO/DET-	Linda Bowen	PHARMACIA & UPJOHN, KALAMAZOO, MI - EIR (06/01/2013 -

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	09/06/2013	DO/DET-CB/	SANOFI	06/30/2013)
2013-6090	08/08/2013 09/06/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Doe J	INDIVIDUAL RECS
2013-6091	08/08/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Robert Rothermund Robert Rothermund	TEVA PHARMACEUTICALS, CINCINNATI, OH - CORRESPONDENCE RE ROBERT ROTHERMUND, PAIGE DURKEE (04/02/2012 - 10/28/2013)
2013-6092	08/08/2013 09/06/2013	FDA/OF/CFSAN/OCD/EOS/	HARRY N. FINKBONE, DABT akzonobel	FCN 845 - UNDERLYING RISK ASSESSMENT FOR VCH (100-30-4) ETC
2013-6093	08/08/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OC/OES/DFOI/ FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	Doe J	COMPLAINT FOLLOW UP
2013-6094	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas G. Kemmy Law Office of Thomas G. Kemmy	INFORMATION FOR HEALTHCARE PROFESSIONALS: FLUOROQUINOLONE ANTIMICROBIAL DRUGS (CERTIFIED)
2013-6095	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DKT 83P-0404 CITIZEN PETITION (CERTIFIED)
2013-6096	08/08/2013 09/06/2013	FDA/OF/CFSAN/OCD/EOS/	HARRY N. FINKBONE, DABT akzonobel	FCN 244 - RISK ASSESSMENT 4-VINYLCYCLOHEXANE ETC
2013-6097	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Jaime Vassallo, LexisNexis CourtLink Document Retrieval	CITIZEN PETITION, RESPONSES RE CANCER WARNING ON COSMETIC TALC (CERTIFIED)
2013-6098	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kevin Whetstone Sunovion Pharmaceuticals Inc.	XOPENEX HFDA - APPROVAL PACKAGE
2013-6099	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Katherine Giannamore The Law Office of Katherine Giannamore, P.A.	DKT 80N-0146
2013-6100	08/08/2013 10/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Patrick Haffey Patrick Haffey	ACTHIB - MANUFACTURING INFORMATION, CONTRACT MANUFACTURING (08/05/2008 - 08/06/2013)

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2013-6101	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	HARRY N. FINKBONE, DABT akzonobel	DKT 1994F-0153 - RISK ASSESSMENT FOR 1,3-BUTADIENE
2013-6102	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	WOCKHARDT - EIR, 483 MOST RECENT (01/01/2013 - 08/06/2013)
2013-6103	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	LIST OF CDER DSI GCP 1 CLINICAL INVESTIGATOR INSPECTIONS IN 2007 BY LOS-DO; LIST OF CDER DSI GCP2 CLINICAL INVESTIGATOR INSPECTIONS IN 2007 BY LOS-DO
2013-6104	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE.	CDER DSI COMPLAINT 1006
2013-6105	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nicole Larch Sandberg, Phoenix and vonGontard	CASE REPORTS 6774803 6776928 6826076 ETC
2013-6106	08/08/2013 09/06/2013	FDA/OF/CFSSAN/OCD/EOS/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	6/6/85 RE ASBESTOS IN TALC FROM QRAC TO W GARY FLAMM (CERTIFIED)
2013-6107	08/08/2013 09/06/2013	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	11/17/94 CITIZEN PETITION SEEKING CARCINOGENIC LABELING ON COSMETIC TALC PRODUCTS (CERTIFIED)
2013-6108	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Maria Tomasch KNXV-TV	ESSURE - COMPLAINTS, INVESTIGATIONS LAST TEN YEARS
2013-6109	08/08/2013 09/06/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ ORA/ ORA/	Kim Aylesworth Aylesworth, Kim	GERBER, FORT SMITH, AR - ENVIRONMENTAL SALMONELLA SURVEILLANCE RESULTS (07/29/2013 - 08/06/2013)
2013-6110	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	RANBAXY, NOIDA - 483 12/21/12; 12/14/12; RANBAXY, VILLAGE TOANSA - 483 12/12/12 ETC

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2013-6111	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K091034 UNREDACTED
2013-6112	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K090254 UNREDACTED
2013-6113	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dennis McLaughlin PHILIPS MEDIZIN SYSTEME	K120579
2013-6114	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tara Burrell InSitu Technologies, Inc	K050814
2013-6115	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caroline Palomeque JMP Securities	UCERIS - AERS
2013-6116	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shalin Jani Aerie Pharmaceuticals Inc.	NDA 204251 - SBA
2013-6117	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K123481 UNREDACTED
2013-6118	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K121275 UNREDACTED
2013-6119	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katrina Fiedler CONVATEC	K112342 UNREDACTED
2013-6120	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Quick Philips Healthcare (Cleveland), Inc.	K113394
2013-6121	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caroline Palomeque JMP Securities	XTANDI - AERS
2013-6122	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/	Heather Behanna JMP Securities	CINRYZE, BERINERT - AERS

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		ALFB/		
2013-6123	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	NUDEXTA (DEXTROMETHORPHAN HBR & QUINIDINE) - AERS 1/12 TO PRESENT
2013-6124	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	BELVIQ (LORCASCRINE HYDROCHLORIDE) - AERS 1/12 TO PRESENT
2013-6125	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	CRZALUTAMIDE - AERS 1/12 TO PRESENT
2013-6126	08/08/2013 09/06/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Eric Thostesen Janssen	LUITPOLD PHARMACEUTICALS, SHIRLEY, NY - 483 (03/01/2012 - 08/05/2013)
2013-6127	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	OCRIPLASMIN - AERS 10/12 TO PRESENT
2013-6128	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	PEMALIDOMIDE - AERS 1/13 TO PRESENT
2013-6129	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	TECFIDERA (DIMETHYL FUMARATE) - AERS 3/13 TO PRESENT
2013-6130	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	KADCYLA (TRASTUZUMAB EMTANSINE) - AERS 2/13 TO PRESENT
2013-6131	08/08/2013 09/06/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOTT FAVUS, MD FAVUS INSTITUTIONAL	AMPYRA FAERS 1/12 TO PRESENT

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		FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RESEARCH LLC	
2013-6132	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ICLUSIG - AER 1/13 TO PRESENT
2013-6133	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	ADCETRIS (BRENTUXIMAB VEDOTIN) AER 2/13 TO PRESENT
2013-6134	08/08/2013 09/06/2013	FDA/OC/OES/DFOI/	ELLIOTT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	FOIA LOG 1/13 TO PRESENT
2013-6135	08/08/2013 09/06/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS	BAYER - 400 SYS K002738; RAPIPOINT 405 SYS K020616
2013-6136	08/08/2013 09/06/2013	FDA/OC/OES/DFOI/	ANDREW HACK, MD MILLENNIUM MANAGEMENT LLC	FOIA LOG 4/13 TO PRESENT
2013-6137	08/08/2013 09/06/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JULIE T. CLIFFORD INEOS OLEFINS AND POLYMERS USA	DMF 1362
2013-6138	08/08/2013 09/06/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	TAPAN OZA QUELLER FISHER ET AL	USPS LABS LLC - JACK3D CORR
2013-6139	08/08/2013 09/06/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PAUL J. WILSON INTERCELL USA INC	IXIARO - CLNCL ASSESSMENT, SUMMARY BASES FOR REGULATORY ACTION (UNREDACTED)
2013-6140	08/08/2013 09/06/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	NOELLE SECHREST NESTLE NUTRITION	GERBER - EAU CLAIRE EIR 9/17-21/12; GATEWAY 6/5-8/12
2013-6141	08/08/2013 09/06/2013	FDA/OF/CFSAN/OCD/EOS/	THOMAS HASKINS GARDERE WYNNE SEWELL LLP	IRRADIATION PROCESS CORR 2006 TO PRESENT
2013-6142	08/09/2013 09/09/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9102
2013-6143	08/09/2013 09/09/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9102 - RESP LTR

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2013-6144	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GHORMLEY 138287 WTSP, ANTHONY T	LAMICTAL 25 MG - AERS
2013-6145	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GHORMLEY 138287 WTSP, ANTHONY T	BUSE BARR - AERS
2013-6146	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	RENEE HAZELWOOD COCHLEAR AMERICAS	COCHLEAR LTD, LANE COVE, AUSTRALIA - EIR 4/8-11/13
2013-6147	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRUSE, JANICE	BARD PERIPHERAL VASCULAR INC, TEMPE, AZ - FINESSE ULTRA BREAST BIOPSY SYS K093068
2013-6148	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	SIBERY, MATTHEW	CIRCULATORY SYS DVC PANEL 4/7/97; CLNCL CHEMISTRY & CLNCL TOXICOLOGY DVCS PANEL 3/20/97; DENTAL PRODS PANEL 2/12/97, ETC - CONFLICT WAIVERS FOR PARTICIPANTS
2013-6149	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELLIOT FAVUS FAVUS INSTITUTIONAL RESEARCH LLC	EXPAREL (BUPIVACAINE LIPOSOME INJ SUSPENSION) - AERS
2013-6150	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	CHANDRAN TIRUVATTAR DR REDDY'S LABORATORIES INC	ACS DOBFAR INFO SA - ZOLEDRONIC ACID NDA 203-231 SBA
2013-6151	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS U.S.A., INC	G & W LABS - METRONIDAZOLE CREAM NDA 77-549, GALDERMA LABS LP - METROCREAM (METRONIDAZOLE) NDA 20-531 SBA
2013-6152	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	APOTEX INC - CANDESARTAN CILEXETIL ORAL TABS ANDA 202-079 APRVL LTR 8/2/13
2013-6153	08/09/2013	FDA/OGROP/ORACE-FO/MIN-		MAMMOGRAPHY FACILITY INSP - 55337, 55130, 55104, ETC

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	09/09/2013	DO/MIN-CB/	HECKADON, RONALD G	RESULTS, VIOLATIONS 3/15/13-8/1/13
2013-6154	08/09/2013	ORA/		STACKER 2 DIET PILLS - Cmplnts 2/1/12 TO 8/5/13
	09/09/2013	ORA/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Doe J	
2013-6155	08/09/2013	FDA/OMPT/CDER/ORP/DIDP/	Bonnie Williams	BLA 103000 S 5050
	09/09/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FOI Services, Inc.	
2013-6156	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer	K093910
	09/09/2013		Theranos, Inc.	
2013-6157	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams	K123700
	09/09/2013		FOI Services, Inc.	
2013-6158	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer	K031359
	09/09/2013		Theranos, Inc.	
2013-6159	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Karshmer	K041148
	09/09/2013		Avisa Pharma, Inc.	
2013-6160	08/09/2013	FDA/OC/OES/DDM/	GLORIA GASKINS	DKT 1994P-0077, 1997P-0386, ETC.
	09/09/2013		KLEINFELD KAPLAN & BECKER	
2013-6161	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer	K103041
	09/09/2013		Theranos, Inc.	
2013-6162	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams	K130079
	09/09/2013		FOI Services, Inc.	
2013-6163	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams	K112820
	09/09/2013		FOI Services, Inc.	
2013-6164	08/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BRETT PARK	INDIVIDUAL RECS (CERTIFIED)
	09/09/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	CONWAY HOMER & CHIN-CAPLAN PC	
2013-6165	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Bonnie Williams	K094030
	09/09/2013		FOI Services, Inc.	
2013-6166	08/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elisa Murillo	P860004

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	09/09/2013		Pearson, Randall & Schumacher, P.A.	
2013-6167	08/09/2013 09/09/2013	FDA/OC/OES/DDM/	TODD MACK WESTLAW COURT EXPRESS	DKT 1988P-0369, 2001P-0122, ETC.
2013-6168	08/09/2013 09/09/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDRH/OCER/DFOI/	Dan Goldsmith X-Laser	LASERWORLD AG, LASERWORLD USA - ACTIONS, WARNING LETTERS, ETC (01/01/2008 - 08/07/2013)
2013-6169	08/09/2013 09/09/2013	FDA/OC/OES/DFOI/	ROBERT P CHARROW GREENBERG TRAURIG LLP	MEDTRONIC XOMED INC - LASER-SHIELD II ENDOTRACHEAL TUBE
2013-6170	08/09/2013 10/11/2013	ORA/ ORA/ ORA/ORO/DFS/ ORA/ORO/DFS/ FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	BLAZE, D'LANIE	FUKUSHIMA DAI' ICHI NUCLEAR PLANT - ACTIVE & INACTIVE MULTIPLE AGREEMENTS, E-MAIL CORR, TESTS, ETC
2013-6171	08/09/2013 09/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PHYLLIS B. KENT KENT ASSOCIATES INC	DR MARTIN ZAIAC - INSP MEMO TO FILE 8/812
2013-6172	08/09/2013 09/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	TED A. NOVICK GAINES NOVICH ET AL	MAUDE RPT 2520313-2011-0018 MEDRAD AVANTA FLUID MGMT INJECTION SYS ANGIOGRAPHIC INJECTOR
2013-6173	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caroline Palomeque JMP Securities	TACFIDERA - AERS
2013-6174	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Bill Anderson Bill Anderson	CEDAR GROVE CHEESE INC, PLAIN, WI - INSPECTION REPORTS SINCE 2000; TEST RESULTS
2013-6175	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joan Gillham Joan Gillham	NDA 017456 - APPROVAL, DISCONTINUATION DATES
2013-6176	08/12/2013 09/10/2013	FDA/OF/CFSAN/OCD/EOS/	A. Philip Leber A. Philip Leber Consulting	FCN 1183

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2013-6177	08/12/2013 09/10/2013	FDA/OGROP/ORPA-FO/SEA-DO/SEA-CB/	Jack Beidleman Idahoan Foods, LLC	IDAHOAN FOODS, LEWISVILLE, ID - INSPECTOR NOTES 08/01/2013
2013-6178	08/12/2013 09/12/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	John Carey FOI Services, Inc.	ORIGINAL LICENSING FILES FOR VACCINE PRODUCTS UNDER THE BIOLOGICS CONTROL 1902
2013-6179	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Scott Marmer Theranos, Inc.	K093972
2013-6180	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Quail Quail, Thomas	N-ACETYLCYSTEINE - AERS
2013-6181	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Phillip Guerra AirwayTec	K760488
2013-6182	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	alexander m m shepherd MD PhD UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO	GLYCOPYRROLATE - AERS
2013-6183	08/12/2013 09/10/2013	FDA/OC/OES/DFOI/	Megan Pickel Beveridge & Diamond, PC	CFSAN FOIA REQUESTS 07/01/2013 TO PRESENT
2013-6184	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	shin kang WELLS FARGO	VIROPHARMA, NETHERLANDS, BELGIUM - 483, WARNING LETTER, EIR (01/01/2013 - 08/09/2013)
2013-6185	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tom Namsavanh IntelGenx Corp.	ANDA 076762
2013-6186	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Haram Kang UNIVERSITY OF ILLINOIS AT CHICAGO	TICAGRELOR - AERS
2013-6187	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Shirley Roberson OMRON HEALTHCARE INC	K122458
2013-6188	08/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sew-Wah Tay	K111576

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	09/10/2013		Libra Medical	
2013-6189	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Frederic mMorneau Duchesnay Inc.	NDA021876
2013-6190	08/12/2013 09/10/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Doe J	SAN FRANCISCO HERB AND NATURAL FOOD CO, FREEMONT, CA - INVESTIGATION RECS 06/01/2012 - 09/30/2012
2013-6191	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Andrew Vaino Retrophin Inc.	NDA 009854
2013-6192	08/12/2013 09/10/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/	Eric Tucker THE ASSOCIATED PRESS	STAR SCIENTIFIC - REPORTS, APPLICATIONS, UPDATED ETC
2013-6193	08/12/2013 09/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	SHOWLINE AUTOMOTIVE PRODUCTS INC, US SOAPS MFG CO, RALEIGH, NC - 483 7/13
2013-6194	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	BELL MOORE LABORATORIES INC, HAMPSTEAD, MD - 483 7/13
2013-6195	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	ROBERT KING FDA NEWS	AVATAR CORP, UNIVERSITY PARK,IL ; HYDROX CHEMICAL CO, ELGIN, IL - 483 7/13
2013-6196	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	SELECTIVE MED COMPONENTS INC, MOUNT VERNON, OH - 483 7/13
2013-6197	08/12/2013 09/10/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	HUMCO HOLDING GROUP INC, TEXARKANA, TX; ESTILL MEDICAL TECHNOLOGIES INC, DALLAS, TX - 483 7/13
2013-6198	08/12/2013 09/10/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	LOS ALAMOS NATIONAL LABORATORY, LOS ALAMOS, NM - 483 7/13
2013-6199	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	BEACON HILL MEDICAL PHARMACY PC, SOUTHFIELD, MI; COOK BIOTECH INC, WEST LAFAYETTE, IN - 483 7/13
2013-6200	08/12/2013 09/10/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	BAUSCH & LOMB, TAMPA, FL; LIFESAVING SYSTEMS CORP, APOLLO BEACH, FL; LENSTEC INC, ST PETERSBURG, FL - 483 7/13
2013-6201	08/12/2013 09/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT KING FDA NEWS	BRISTOL MYERS SQUIBB, ANAGNI, ITALY; SANOFI AVENTIS DEUTSCHLAND GMBH, FRANKFURT AM MAIN, GERMANY; ACS DOBFAR SPA, MILAN, ITALY - 483 7/13

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2013-6202	08/12/2013 09/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	SANOFI AVENTIS DEUTSCHLAND GMBH, FRANKFURT AM MAIN, GERMANY; UNIDUS CORP, CHUNGBUK, SOUTH KOREA; BRAHMS GMBH, HENNIGSDORF, GERMANY - 483 7/13
2013-6203	08/12/2013 09/10/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	ESSEX CYROGENICS OF MISSOURI, KANSAN CITY, MO; DENTAL DESIGNS LABORATORY, LINCOLN, NE; GLOBAL MEDICAL HOLDINGS LLC, ADEL, IO - 483 7/13
2013-6204	08/12/2013 09/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	BIOELECTRIC RESEARCH CORP, PASADENA, CA; KDL PRECISION MOLDING, PACOIMA, CA; DEN MAT HOLDINGS LLC, LOMPOC, CA - 483 7/13
2013-6205	08/12/2013 09/10/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	AMRI BURLINGTON INC, BURLINGTON, MA; SIRTEX WILMINGTON LLC, WILMINGTON, MA; NOVA BIOMEDICAL CORP, BILLERICA, MA - 483 7/13
2013-6206	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	ROBERT KING FDA NEWS	ASHLAND SPECIALITY INGREDIENTS, CHATHAM, NJ; PERMA PURE LLC, TOMS RIVER, NJ - 483 7/13
2013-6207	08/12/2013 09/10/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	AIONEX INC, GOODLETTSVILLE, TN; VIRTUAL SUN LLC, JEMISON, AL - 483 7/13
2013-6208	08/12/2013 09/10/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY; AMNEAL PHARMACEUTICALS, BROOKHAVEN, NY; PINE PHARMACY & HOME CARE PRODUCTS CTR INC, WILLIAMSVILLE, NY - 483 7/13
2013-6209	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	PIRAMAL CRITICAL CARE INC, BETHLEHEM, PA; DRAEGER MEDICAL SYSTEMS INC, TELFORD, PA; DRAEGER MEDICAL INC, TELFORD, PA - 483 1/13
2013-6210	08/12/2013 09/10/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	FORMULATION TECHNOLOGY INC, OAKDALE, CA; BIO RAD LABORATORIES INC, HERCULES, CA; TOPCON MEDICAL LASER SYSTEMS INC, SANTA CLARA, CA - 483 7/13
2013-6211	08/12/2013 09/10/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	NEO METRICS INC, PLYMOUTH, MN; INCONTROL MEDICAL LLC, BROOKFIELD, WI - 483 7/13
2013-6212	08/12/2013 09/10/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	UNIV OF WASHINGTON PET RADIOCHEMISTRY LABORATORY, SEATTLE, WA; KIRKMAN GROUP INC, LAKE OSWEGO, OR; ENDOGASTRIC SOLUTIONS INC, REDMOND, WA - 483 7/13
2013-6213	08/12/2013 09/10/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	GASCO INDUSTRIAL, GURABO, PR; PFIZER PHARMACEUTICALS, VEGA BAJA, PR - 483 7/13
2013-6214	08/13/2013 09/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Danielle Stampley Labaton Sucharow LLP	INTUITIVE SURGICAL - EIR, WARNING LETTERS, 483 ETC (01/01/2011 - 08/12/2013)

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		FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/		
2013-6215	08/13/2013 09/11/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Danielle Stampley Labaton Sucharow LLP	INTUITIVE SURGICAL - APPROVAL RECS, INSPECTION RECS
2013-6216	08/13/2013 09/11/2013	ORA/ ORA/	JOSHUA GAYNOR CBS NEWS	SPECIALTY COMPOUNDING, LLC, CEDAR PARK, TX - 483
2013-6217	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Robinson BluePoint Laboratories	WOCKHARDT LIMITED, MAHARASHTA, INDIA - 483 (07/01/2013 - 08/12/2013)
2013-6218	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hllary Healy Hilary Healy	XOLAIR - AERS
2013-6219	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Sietsema Sietsema, William	NDA 21743 S0003
2013-6220	08/13/2013 09/11/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Doe J	INDIVIDUAL RECS
2013-6221	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Soma Das The Economic Times, The Times of India	USV LTD, MUMBAI, INDIA - 483 06/01/2012 - 08/12/2013
2013-6222	08/13/2013 09/11/2013	ORA/ORM/ ORA/ORM/	Mark Prinz Registrar Corp	FOREIGN FOOD FACILITIES THAT RECEIVED 483 FROM INSPECTION 07/01/2013 - 07/31/2013
2013-6223	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	David Karshmer Avisa Pharma, Inc.	K011668, K130524
2013-6224	08/13/2013 09/11/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SW-FO/KAN-	Anthony L. Osborn Goosmann Law Firm, PLC	CHONDROITIN SULFATE, TRYPSIN - PRODUCTION, MANUFACTURE, DISTRIBUTION ETC

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		DO/KAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/ FDA/OF/CFSAN/OCD/EOS/		
2013-6225	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	Desmond Jenson Tobacco Control Legal Consortium	CTP FOIA REQUEST LOG 06/22/2009 - 08/12/2013
2013-6226	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	CHLORDIAZEPOXIDE, AMITRIPTYLINE HYDROCHLORIDE - SBA
2013-6227	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 08/05/2013 - 08/09/2013
2013-6228	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thaddeus Ritch EOHSI - Rutgers RWJMS	FDA DRUG SAFETY COMMUNICATION RE ANTIMALARIAL DRUG MEFLOROQUINE HYDROCHLORIDE - NOTES, PROCEDURES, DATA REVIEWED ETC
2013-6229	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	JANUVIA (SITAGLIPTIN) NDA 21-995 - MEDICAL, SCIENTIFIC SAFETY RVWS, CORR, MINS, ETC
2013-6230	08/13/2013 09/11/2013	FDA/OC/OES/DDM/	CHRISTOPHER BRENNAN WESTLAW COURT EXPRESS	FDA BIOEQU HEARING - TRANS, EXHIBIT 4 9/29/86-10/1/86
2013-6231	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	RONALD G VAN VALEN NOVARTIS PHARMACEUTICAL CORP	FUJIREBIO DIAGNOSTICS INC, MALVERN, PA - ARCHITECT SIROLIMUS ASSAY; K070822
2013-6232	08/13/2013 09/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MITCHELL, ERIC	ONE LAMBDA INC, CANOGA PARK, CA - HLA FUSION SOFTWARE BK120014
2013-6233	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	LOFGREN, TRACY	CONMED CORP, UTICA, NY - INTRAVASCULAR CATHETER SECUREMENT K935389 ACCEPTANCE LTR, RPT
2013-6234	08/13/2013	FDA/OMPT/CDRH/OCER/DFOI/		INDIVIDUAL RECS

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	09/11/2013		Doe J	
2013-6235	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marion Tong MPT Consulting Marion Tong	K080451, K040763, K002680
2013-6236	08/13/2013 09/11/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Doe J	ETHICON - US/MN-SUTURE ABOSRBABLE, NON ABSORBABLE ENTRY AV3-0040036-1
2013-6237	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAVIER COLLAZO	VENTUS MEDICAL INC - PROVENT PROFESSIONAL SLEEP APNEA THERAPY K090398
		FDA/OC/OES/DFOI/	RespCare	
2013-6238	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/	PHYLLIS B KENT	DR MARTIN ZAIAC - MEMO 8/8/12
		FDA/OMPT/CDER/GRP/DIDP/	KENT ASSOCIATES INC	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-6239	08/13/2013 09/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Andrea C. Williams	STUDIES SHOWING EFFICACY OF ULTHERA MACHINE ON SAGGING/WRINKLES NECK SKIN
		FDA/OC/OES/DFOI/	Andrea C. Williams	
2013-6240	08/13/2013 09/11/2013	ORA/	SARAH SORSHER	SPECIALTY COMPOUNDING LLC - 483 MINOR DELETIONS
		ORA/	PUBLIC CITIZEN (HEALTH RESEARCH GROUP)	
2013-6241	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/	DON J MIZERK	TEVA PHARMS, ACTAVIS ELIZABETH, BARR LABS INC - AMPHETAMINE ASPARTERTE, AMPHETEMINE SULFATE, DEXTROAMPHETAMIN SACCHARATE ANDA 77-4488, ANDA 77302, ANDA 76536, ETC APRVL LTR 4/29/13, 6/22/12, 2/12/13
		FDA/OMPT/CDER/GRP/DIDP/	HUSCH BLACKWELL LLP	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-6242	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/	DAVID M HOFFMEISTER	RANBAXY LABORATORIES LTD, MOHALI, INDIA - ESOMEPRAXOLE MAGESIUM ANDA 77-830 APRVL LTR 2/5/08, 483 1/1/12, 8/9/13
		FDA/OMPT/CDER/GRP/DIDP/	WILSON SONSINI ET AL	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-6243	08/13/2013 09/11/2013	FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER BRENNAN	JANUMET (SITAGLIPHTIN (METFORMIN) NDA 22-044 - MEDICAL, SCIENTIFIC RVWS, CORR, MINS, ETC
		FDA/OMPT/CDER/GRP/DIDP/	WESTLAW COURT EXPRESS	
		FDA/OMPT/CDER/GRP/DIDP/		
		FDA/OMPT/CDER/GRP/DIDP/		
2013-6244	08/13/2013 09/11/2013	FDA/OF/CFSAN/OCD/EOS/	EDWARD B GERARD	STAR SCIENTIFIC - ANATABLOC DEVELOPMENT, PROMOTION, REGULATION/SALE
			ROBBINS ARROYO LLP	
2013-6245	08/13/2013 09/11/2013	ORA/	DONALD BLUE	ENTRY 20130809-1 7/16/13-8/15/13
		ORA/	GLOBAL TRADE INTELLIGENCE INC	
		FDA/OGROP/ORA/ORO/DIOP/		

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2013-6246	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	ANAIS VAILLANT MUCKROCK NEWS	AIRLINE DRINKING WATER INSP (PREVIOUSLY RELEASED)
2013-6247	08/13/2013 09/11/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	MENTHOL VERSUS NONMENTHOL CIGARETTES - RPTS, ANALYSES, RESULTS, ETC 7/24/13
2013-6248	08/13/2013 09/11/2013	FDA/OMPT/OSMP/OOPD/	ALAN CASH Terra Biological LLC	ORBAN BIOTECH LLC, BROOKLINE, MA - ORENCIA (ABATACEPT) ORPHAN DRUG APPL 5/30/13
2013-6249	08/13/2013 09/11/2013	FDA/OMPT/OSMP/OOPD/	ALAN CASH Terra Biological LLC	PENTWECH PHARMACEUTICALS INC, BUFFALO GROVE, IL - APOMORPHINE ORPHAN DRUG APPL 7/17/95
2013-6250	08/13/2013 09/11/2013	FDA/OF/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	KRAFT, WISHBONE, HIDDEN VALLEY SALAD DRESSING, ETC - CAERS 1969 TO 2013
2013-6251	08/13/2013 09/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	FRANK S WILTON AMERICAN ASSOCIATION OF TISSUE BANKS	RECOMMENDATION OF THE TISSUE REFERENCE GROUP (TRG) - STAKEHOLDER SUBMISSIONS 2013
2013-6252	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	Margaret Sestrom PFIZER	483 for Dr. Malhotra B2061028 9002/018 Site 1055 Malhotra QR 72431
2013-6253	08/13/2013 09/11/2013	FDA/OC/OES/DFOI/	shin kang WELLS FARGO	pre-approval inspection form 483 and company response to the form 483 for Biomarin Pharmaceutical
2013-6254	08/14/2013 09/12/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203565
2013-6255	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	Daniel Machian Los Angeles Department of Coroner	BREAST IMPLANT MCGHAN 168 300CC SN 11252169 LOT 1031234
2013-6256	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rick Miller ProtoMED Inc	K103136
2013-6257	08/14/2013 09/12/2013	FDA/OF/CFSAN/OCD/EOS/	Kevin Fries COSMETIC INGREDIENT REVIEW	PAFA DATABASE
2013-6258	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Daniel Machian Los Angeles Dept of Coroner	ALLERGAN, Style 68MP 390cc, Lot 1838586
2013-6259	08/14/2013 09/12/2013	FDA/OF/CFSAN/OCD/EOS/	Duane Stanford BLOOMBERG NEWS	HERBALIFE, ENSURE, SLIM-FAST - AERS
2013-6260	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Jason A Dean Hulsey Oliver & Mahar, LLP	2013-4472 (CERTIFIED)

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2013-6261	08/14/2013 09/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric D. tindal Nidey Erdahl Tindal & Fisher, PLC	ACORDA THERAPEUTICS WARNING LETTER - COMPANY RESPONSE ETC (07/01/2013 - 08/13/2013)
2013-6262	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-4703
2013-6263	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-1338
2013-6264	08/14/2013 09/12/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	Fenella Cochrane Parnell Corporate Services US Inc	TEST RESULTS
2013-6265	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Indeep Aulak Response Point of Care, Inc.	K121214
2013-6266	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Andrea Ferrenz Celltex Therapeutics Corporation	CELLTEX THERAPEUTICS CORPORATION - FOIA REQUESTS (03/18/2011 - 08/30/2013), 2012-5692, 2012-8891, 2013-2838
2013-6267	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jamie Ridner COOK INCORPORATED	LATECBA DEVICE - IDE, SAFETY AND EFFECTIVENESS DATA
2013-6268	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brian Hewko Brian Hewko	510K CLEARED FOR BONE WEDGE OR RECONSTRUCTION DEVICE MADE FROM PEEK BASED MATERIALS
2013-6269	08/14/2013 09/12/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	George Perham Dickinson Brands	ANALYTICAL RESULTS
2013-6270	08/14/2013 09/12/2013	ORA/OE/ ORA/OE/	Jeremy Graston Jeremy Graston	ARCHIVED RECALL DATA BEFORE 2004
2013-6271	08/14/2013 09/12/2013	FDA/OC/OES/DFOI/	Bennie Lee Cheatham, Jr Bennie Lee Cheatham, Jr.	PRESCRIPTION INFORMATION
2013-6272	08/14/2013	FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE	BACTROBAN NASAL OINTMENT NDA 50-703 APRVL LTR, LBLG, MED RVW

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	09/12/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	EAS Consulting Group, LLC	
2013-6273	08/14/2013 09/12/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	HENRY KIANG, Ph.D. PHARMOUT	FEI 3000323451 5/16-23/12
2013-6274	08/14/2013 09/12/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	PATRICK ORR PATRICK ORR BARRISTER & SOLICITOR	VITEK INC - IMPLANT DOCS
2013-6275	08/14/2013 09/30/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	FORD, RAHMAN A	AUTOLOGOUS (HOMOLOGOUS) STEM CELLS - POLICIES, PROCEDURES, CLNCL USE, ETC
2013-6276	08/14/2013 09/12/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	COLLEEN GRACE DONOFRIO BABST CALLAD CLEMENTS ET AL	GILES CHEMICAL, WAYNESVILLE, NC - EIR 8/12
2013-6277	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	LESTER MAYERS, MD Pace University	IMPACT CONCUSSION ASSESSMENT PROGRAM 3/12
2013-6278	08/14/2013 09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	ADAM M. DLUGACZ HPM&B ATTYS AT LAW	ST JUDE MEDICAL 6F ANGIO SEAL VASCULAR CLOSURE DVC 2000 TO 2013
2013-6279	08/14/2013 09/12/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LTRS TO MICHAEL M LANDA 6/3/13
2013-6280	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Albin Pearson Albin Pearson	REGEAR LIFE SCIENCES REBOUND - CLEARANCE RECS
2013-6281	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	James Chen CREDIT SUISSE	TECFIDERA - AERS
2013-6282	08/15/2013 09/13/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Deborah Guercio THE BROOKLYN HOSPITAL CENTER	MORRELL M AVRAM - INSPECTION RECS 1/28/04
2013-6283	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sean Higgins ANDREWS & THORNTON	MITOMYCIN - AERS
2013-6284	08/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Mary Gustafson	LETTER FROM FDA TO PPTA 8/5/13

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	09/13/2013		PPTA	
2013-6285	08/15/2013 09/13/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Gretchen Ramos Ramos, Gretchen A	POMEGRANATE SEED RECALL - INVESTIGATIVE RECS
2013-6286	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Prudhomme Naval Aerospace Medicine Institute	ZESTRIL - AERS FROM PHASE 1 AND 2 STUDIES
2013-6287	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anita Zacherl for OsteoMed OSTEOMED CORP	K924138
2013-6288	08/15/2013 09/13/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	JET CIGARETTES - REGISTRATION, PRODUCT LISTING, INGREDIENTS ETC
2013-6289	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Christopher B. Swanson ADVANCED STERILIZATION PRODUCTS	K123768
2013-6290	08/15/2013 09/13/2013	FDA/OC/OES/DDM/	Larry Biegelsen Wells Fargo Securities, LLC	DRAFT GUIDANCE RE CYCLOSPORINE - COMMENTS 06/20/2013 - 08/20/2013
2013-6291	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K030289
2013-6292	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K984053
2013-6293	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson HOTSWAP STOCKHOLM AB	K914735
2013-6294	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson Hotswp Stockholm AB	K962928
2013-6295	08/15/2013 09/13/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Joanna McCracken Hall Booth Smith, P.C.	MAIN STREET FAMILY PHARMACY, NEWBERN, TN - INSPECTION RECS (03/15/2013 - 08/14/2013)
2013-6296	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachelle Lyon JANUS CAPITAL GROUP INC	TECFIDERA - AERS
2013-6297	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Manapol Law Offices of Brian D. Witzer, Inc.	ANDA 065156

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6298	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph E. Schwarz Natus Medical Incorporated	K111737
2013-6299	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Jon Mulberg Animas Corporation	ANIMUS CORPORATION - EIR ATTACHMENT 5 3/25/2013 - 4/12/2013
2013-6300	08/15/2013 09/13/2013	FDA/OF/CFSAN/OCD/EOS/	ALISON YOUNG USA TODAY	WOW (REUMOFAN) - CAERS 151929, 151974, 153108. ETC
2013-6301	08/15/2013 09/13/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	JENNIFER ZACHARY COVINGTON & BURLING LLP	LLOYD LLC - 483 4/16/13
2013-6302	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	FRANK E PISCITELLI JR PISCITELLI LAW FIRM	BOSTON SCIENTIFIC - GREENFIELD VENA CAVA FILTER MDRS
2013-6303	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBYN S MAGUIRE NUTTER MCCLENNEN & FISH LLP	DEPUY ORTHOPAEDICS INC - PINNACLE HIP IMPLANTS, METAL-ON-METAL PROSTHETIC HIP IMPLANTS RECS; WALLACE GREGORY SAWYER PHD, MARTIN K MCDERMOTT PHD, JOHN A TICHY PHD CORR, ETC
2013-6304	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CRAIG TRAUTMAN INTAGRAS INC	DRUG LISTINGS NOT POSTED ON THE NATIONAL LIBRARY OF MEDICINE (NLM) WEBSITE, ESTABLISHMENT REGISTRATIONS, LABELER CODES
2013-6305	08/15/2013 09/13/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ OC/OCC/	KEN CUMMINS CAPITOL GROUP	HEATHER BRESCH, MYLAN PHARMACEUTICALS INC - VISITATION LOGS FOR OFFICE OF THE COMMISSIONER, GENERAL COUNSEL, OFFICE OF GENERIC DRUGS, ETC 1/11 TO PRESENT
2013-6306	08/15/2013 09/13/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANDY J KAMYKOWSKI GREENSFELDER HEMKER & GALE PC	CYNOSURE SMART LIPO - MDRS
2013-6307	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MANDY J KAMYKOWSKI GREENSFELDER HEMKER & GALE PC	SODIUM BICARBONATE - AERS
2013-6308	08/15/2013 09/13/2013	FDA/OC/OES/DDM/	DANYSH, KURT	PROZAC - CITIZNES COMMISSION ON HUMAN RIGHTS CITIZEN PETITION 10/11/90; PUBLIC CITIZEN HEALTH RESEARCH GROUP CITIZEN PETITION 5/91, ETC

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2013-6309	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANYSH, KURT	PAXIL, ZOLOFT, CELEXA, ETC - AERS
2013-6310	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	STEVEN ELDER CAMPBELL TOBACCO REHANDLING COMPANY INC	CELTAB INC, MADISON, IN - EIR
2013-6311	08/15/2013 09/13/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SPENCER #13716219, NATHAN	ABILIFY, SEROQUEL - SAFETY STANDARDS, PUBLIC HEALTH ADVISORY, HEARINGS, ETC
2013-6312	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	THOMPSON, RAY	AGFA HEALTHCARE CORP, CARLSTADT, NJ 3/11-29/13; BIO-MED USA INC, PATERSON, NJ 1/9-23/13; GENESIS BPS LLC, HACKENSACK, NJ 2/4-11/13, ETC - 483S
2013-6313	08/15/2013 09/13/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	THOMPSON, RAY	BALASSA LABORATORIES INC, PORT ORANGE, FL 2/13- 19/13; CARIBE NATURAL LLC, MIAMI, FL 3/5-18/13; INSIGHT INSTRUMENTS INC, STUART, FL, ETC - 483S
2013-6314	08/15/2013 09/13/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	THOMPSON, RAY	CONTINENTAL MANUFACTURING CHEMIST INC, MADRID, IA 3/6-15/13; CENTRAL ADMIXTURE PHARMACY SERVICES INC, KANSAS CITY, MO 2/19-27/13; MEGA SUN INC, ST LOUIS, MO 2/28/13-3/6/13, ETC - 483S
2013-6315	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	THOMPSON, RAY	AMERICAN ANTIBIOTICS INC, BALTIMORE, MD 3/5-28/13; MATH RESOLUTION LLC, COLUMBIA, MD 1/7-25/13; TRINITY STERILE INC, SALISBURY, MD 2/12-13/13, ETC - 483S
2013-6316	08/15/2013 09/13/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	THOMPSON, RAY	SPEED LABORATORY INC, BUFORD, GA 1/2-8/13; AMBIOPHARM INC, NORTH AUGUSTA, SC 3/26-28/13; STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC 3/18-25/13, ETC - 483S
2013-6317	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	THOMPSON, RAY	CATALENT PHARMA SOLUTIONS LLC, WINCHESTER, KY 1/28/13-2/5/13; PI PHARMA INC, CAMPTON, KY 1/29/13- 2/22/13; ORTHOHELIX SURGICAL DESIGNS INC, MEDINA, OH 1/15-31/13, ETC - 483S
2013-6318	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	THOMPSON, RAY	ALMA LASERS INC, BUFFALO GROVE, IL 1/17-29/13; ENDOPLUS INC, BUFFALO GROVE, IL 2/21-26/13; HYDRITE CHEMICALS, UNIVERSITY PARK, IL 3/7-18/13, ETC - 483S
2013-6319	08/15/2013 09/13/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	THOMPSON, RAY	BIOMEDIX INC, BLOOMINGTON, IN 2/5/13-3/4/13; ASPEN SURGICAL PRODUCTS INC, CALEDONIA, MI 2/4-15/13; CAYMAN CHEMICAL COMPANY INC, ANN ARBOR, MI 2/21- 28/13, ETC - 483S

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2013-6320	08/15/2013 09/13/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	THOMPSON, RAY	COOPER SURGICAL INC, TRUMBULL, CT 12/17/12-1/16/13; BFS PHARMA INC, RANDOLPH, MA 12/10/12-1/17/13; BIOGEN IDEC INC, CAMBRIDGE, MA 3/4-15/13, ETC - 483S
2013-6321	08/15/2013 09/13/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	THOMPSON, RAY	LEE AND COMPANY, FORT SMITH, AR 2/19-21/13; ALOE VERA OF AMERICA INC, DALLAS, TX 12/14/12-1/11/13; MID-CONTINENT PACKAGING INC, ENID, OK 1/17-24/13, ETC - 483S
2013-6322	08/15/2013 09/13/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	THOMPSON, RAY	BEZWECKEN INC, WILSONVILLE, OR 11/27/12-1/7/13; GENESIS NORTHWEST INC, PORTLAND, OR 1/2-18/13; ENDOGASTRIC SOLUTIONS INC, REDMOND, WA 1/16-25/13, ETC - 483S
2013-6323	08/15/2013 09/13/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	THOMPSON, RAY	AGROPHARMA LABORATORIES INC, SALINAS, PR 2/25/13-3/20/13; CARDINAL HEALTH PR 218 INC, ANASCO, PR 1/22-29/13; JANSSEN ORTHO LLC, GURABO, PR 1/17/13-2/22/13, ETC - 483S
2013-6324	08/15/2013 09/13/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	THOMPSON, RAY	ADVANCE PHARMACEUTICAL INC, HOLTSVILLE, NY 1/3-11/13; AMRI RENSSELAER INC, RENSSELAER, NY 1/23-30/13; HYPERBARIC TECHNOLOGIES INC, AMSTERDAM, NY 2/11-20/13, ETC - 483S
2013-6325	08/15/2013 09/13/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	THOMPSON, RAY	ALLERGAN INC, IRVINE, CA 3/12-21/13; AMRON INTERNATIONAL, VISTA, CA 2/13-19/13; OPMX LLC, SAN DIEGO, CA 1/16/13-2/20/13, ETC - 483S
2013-6326	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	THOMPSON, RAY	SPRAY-TEK INC, BETHLEHEM, PA 3/13-18/13; TROY MANUFACTURING INC, HAZLE TOWNSHIP, PA 2/6-12/13 - 483S
2013-6327	08/15/2013 09/13/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	THOMPSON, RAY	EXXON MOBIL CHEMICAL CO, BATON ROUGE, LA 3/9-21/13; DOW CHEMICAL CO, PLAQUEMINE, LA 2/7-13/13; PETNET SOLUTIONS INC, COVINGTON, LA 1/14-17/13, ETC - 483S
2013-6328	08/15/2013 09/13/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	THOMPSON, RAY	ARIZANT HEALTHCARE INC, EDEN PRAIRIE, MN 3/14-28/13; ESCALON MEDICAL CORP, NEW BERLIN, WI 2/27/13-3/7/13; STEARNS PACKAGING CORP, MADISON, WI 3/11-20/13, ETC - 483S
2013-6329	08/15/2013 09/13/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	THOMPSON, RAY	AMGEN INC, BOULDER, CO 3/18-29/13; NOVARAD CORP, AMERICAN FORK, UT 3/4-11/13; BIOVISION TECHNOLOGIES LLC, GOLDEN, CO 2/11-20/13, ETC - 483S
2013-6330	08/15/2013 09/13/2013	FDA/OC/OES/DFOI/	JACQUELINE B KORT COOLEY LLP	2013-1699, 2013-2674, 2013-3623
2013-6331	08/15/2013 09/13/2013	FDA/OC/OES/DFOI/	JACQUELINE B KORT COOLEY LLP	2013-5596
2013-6332	08/16/2013 09/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN Waters Corporation	DE NOVO - ORTHOPHOSPHATE TEST SYS K122282

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2013-6333	08/16/2013 09/16/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN Waters Corporation	THERMO SCIENTIFIC QMS TACROLIMUS IMMUNOASSAY, TACROLIMUS CALIBRATORS K123343
2013-6334	08/16/2013 09/16/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	MICRA BIOTECHNOLOGIES INC, RIVER EDGE, NJ - EIR, 483, CO 3/04/13
2013-6335	08/16/2013 09/16/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LINCARE INC, OTTAWA, KS - EIR, 483, CO RESP 01/16/13
2013-6336	08/16/2013 09/16/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	FERRO PFANSTIEHL INC, WAUKEGAN, IL - EIR, 483, CO 02/11/13
2013-6337	08/16/2013 09/16/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHARLES RIVER ENDOSAFE, CHARLESTON, SC - EIR, 483, CO RESP 01/15/13
2013-6338	08/16/2013 09/16/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIRCHWOOD LABORATORIES INC, EDEN PRAIRIE, MN - EIR, 483, CO RESP 01/07/13
2013-6339	08/16/2013 09/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	AMRI RENSSLAER INC, RENSSLAER, NY - EIR, 483, CO RESP 01/30/13
2013-6340	08/16/2013 09/16/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	AMPHASTAR PHARMACEUTICALS INC, RANCHO CUCAMONGA, CA - EIR, 483, CO RESP 02/06/13
2013-6341	08/16/2013 09/16/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	JT INDUSTRIES, LOS ANGELES, CA - EIR, 483, CO RESP 01/18/13
2013-6342	08/16/2013 09/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	AMES GOLDSMITH CORP, GLENS FALLS, NY - EIR, 483, CO RESP 01/10/13
2013-6343	08/16/2013 09/16/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	DERCHER ENTERPRISES INC (GORDON LABS), UPPER DARBY, PA - EIR, 483, CO RESP 01/18/13
2013-6344	08/16/2013 09/16/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CHROMAC RESEARCH INC, SOMERSET, NJ - EIR, 483, CO RESP 01-31/13
2013-6345	08/16/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAYMAN CHEMICAL CO INC, ANN ARBOR, MI - EIR, 483, CO RESP 02/28/13
2013-6346	08/16/2013 09/16/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	APRIA HEALTHCARE INC (KNOLL PATIENT SUPPLY), TOPEKA, KS - EIR, 483, CO RESP 01/09/13
2013-6347	08/16/2013 09/16/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	THE MENTHOLATUM CO, ORCHARD PARK, NY - EIR, 483, CO RESP 02/20/13
2013-6348	08/16/2013 09/16/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	SPEED LABORATORY INC, BUFORD, GA - EIR, 483, CO RESP 01/08/13

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2013-6349	08/16/2013 09/16/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ADELE GILPIN ARNOLD & PORTER	TARCEVA (ERLOTINIB HCL) NDA 02-1743 - SBA
2013-6350	08/16/2013 09/16/2013	ORA/ ORA/	DR ROBERT L LYTTLE DDS	WARNING LTR MIN 11-14 03/03/11 - NOT REMOVING FROM AGENCY'S WEBSITE RECS
2013-6351	08/16/2013 09/16/2013	FDA/OF/CFSAN/OCD/EOS/	MIWTCHELL S FUERST FUERST ITTLEMAN DAVID & JOSEPH PL	DRAFT GUIDANCE FOR INDUSTRY: REQUENTLY ASKED QUESTIONS ABOUT MEDICAL FOODS - DIABETWES MELLITUS TPE 1 & 2 COMMS, QUESTIONS, RECS, ETC
2013-6352	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Eric Arnali, Inc.	K002679, K030531, K952794 ETC
2013-6353	08/19/2013 09/17/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Joyce Edwards Edwards, Joyce	RTI BIOLOGICS, INC, ALACHUA, FL - 483 (01/01/2011 - 08/15/2013)
2013-6354	08/19/2013 09/17/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1169
2013-6355	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Cunningham Dechra Ltd Dechra Ltd	NDA# 020803
2013-6356	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Cunningham Dechra Ltd Dechra Ltd	NDA 020583, 020841, 200738 ETC
2013-6357	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jan Cunningham Dechra Ltd Dechra Ltd	HYALURONATE SODIUM - AERS
2013-6358	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stryker Endoscopy STRYKER ENDOSCOPY	K111154
2013-6359	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Eric Joseph JMP Securities	ICLUSIG - AERS

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2013-6360	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Smith B. Braun Medical Inc.	K130416
2013-6361	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Freddy Mejia Ansell Healthcare Products LLC	NDA 019028, ANDA 073695
2013-6362	08/19/2013 09/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Shandin Duffer Baker Sterchi Cowden & Rice, LLC	NEVADA HEART AND VASCULAR CENTER, LAS VEGAS, NV - INVESTIGATION RECS 01/01/2011 - 01/01/2013
2013-6363	08/19/2013 09/17/2013	FDA/OC/OES/DDM/	Janet B. Arrowsmith Arrowsmith Consulting LLC	CLOZAPINE - ADVISORY COMMITTEE TRANSCRIPT AND BACKGROUND MATERIALS
2013-6364	08/19/2013 09/17/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Kathryn Dore JONES DAY	INDIVIDUAL RECS
2013-6365	08/19/2013 09/17/2013	FDA/OC/OES/DDM/	Adrian Chew Pinsent Masons LLP	PULMONARY ALLERGY DRUGS ADVISORY COMMITTEE - TRANSCRIPTS 01/01/1992 - 12/02/1996
2013-6366	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Russin Diabetes Sentry Products, Inc.	P810044 S005
2013-6367	08/19/2013 09/17/2013	CVM/OCD/	John Russell The Indianapolis Star	CVM INVESTIGATION LOG RE RX DRUGS 01/01/1990 - 08/15/2013 ;
2013-6368	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joakim Aske Aske, Joakim	WOCKHARDT LIMITED - 483, RESPONSES 01/01/2000 - 08/16/2013
2013-6369	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ketaki Gokhale BLOOMBERG NEWS	WOCKHARDT LTD - 483 08/16/2011 - 08/16/2013
2013-6370	08/19/2013 09/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Myron Holubiak Myron Holubiak	TRINAM - PHASE II AND PHASE III MEETINGS
2013-6371	08/19/2013 09/17/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CTP/OD/	Eric Tucker THE ASSOCIATED PRESS	STAR SCIENTIFIC - AERS

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2013-6372	08/19/2013 09/17/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF 483S 07/18/2013 - 08/16/2013
2013-6373	08/19/2013 09/17/2013	FDA/OF/CFSAN/OCD/EOS/	Sean Higgins ANDREWS & THORNTON	DMAA - AERS
2013-6374	08/19/2013 09/17/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	DEFOAMING AGENTS FOR POTATOES - OPINION LETTERS, SUBMISSIONS, REVIEWS ETC
2013-6375	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tuvia Rotberg Levisohn Berger, LLP	K011488
2013-6376	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Donald L. Bredle, PhD University of Wisconsin - Eau Claire	HESPAN, HEXTEND, VOLUVEN - AERS
2013-6377	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dong Liang TEXAS SOUTHERN UNIVERSITY/ SCHOOL OF PHARMACY	K123050, K123844
2013-6378	08/19/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Blake Goodner BRIDGER BIOMED INC	GILEAD SCIENCES, FOSTER CITY, CA - 483, RESPONSE, WARNING LETTERS 01/03/2012 - 08/16/2013
2013-6379	08/19/2013 09/17/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	Peter Waldran BAYER HEALTHCARE	LUITPOLD PHARMACEUTICALS, SHIRLEY, NY - EIR, 483, WARNING LETTER
2013-6380	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Blake Goodner BRIDGER CAPITAL LLC	TORNIER NV, EDINA, MN - 483, RESPONSE, WARNING LETTER 01/03/2012 - 08/16/2013
2013-6381	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Kevin Liu UMI INTERNATIONAL	K113198
2013-6382	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Melissa Brady Brady, Melissa	INNOVATIVE DENTAL LABORATORY SERVICES, INC, BUFFALO, NY - REGISTRATION
2013-6383	08/19/2013 09/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bao Le ARIAD PHARMACEUTICALS INC	ICLUSIG - AERS
2013-6384	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2012-3406

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2013-6385	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5440 REQUEST LETTER
2013-6386	08/19/2013 09/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Katherine Giannamore The Law Office of Katherine Giannamore, P.A.	K862875
2013-6387	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5436 REQUEST LETTER
2013-6388	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5275 - REQUEST LETTER ONLY
2013-6389	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5783 - REQUEST LETTER ONLY
2013-6390	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5624 - REQUEST LETTER ONLY
2013-6391	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5669 - REQUEST LETTER
2013-6392	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5790 - REQUEST LETTER
2013-6393	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5176 - REQUEST LETTER
2013-6394	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5883 - REQUEST LETTER
2013-6395	08/19/2013 09/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5187 - REQUEST LETTER
2013-6396	08/19/2013 09/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	DR. AIFREDO FALCONE, PISA, ITALY - EIR, 483S CO RESP 07/18/12

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2013-6397	08/19/2013 09/17/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	QUALTEX LABS, SAN ANTONIO, TX - EIR, 483, CO RES0P 02/19/13
2013-6398	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PADDOCK LABORATORIES LLC, MINNEAPOLIS, MN - EIR, 483, CO RESP 02/06/13
2013-6399	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHAICKLEY THOMSON REUTERS	NORTH AMERICAN SCIENCE ASSOCIATES INC, NORTHWOOD, OH - EIR, 483, CO RESP 01/18/13
2013-6400	08/19/2013 09/17/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	MOBIUS THERAPEUTICS LLC, SAINT LOUIS, MO - EIR, 483, CO RESP 01/17/13
2013-6401	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	WILLIAM J REHEAD MD, MILWAUKEE, WI - EIR, 483S, CO RESP 05/03/12
2013-6402	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	KNOX COMMUNITY HOSPITAL IRB, MOUNT VERNON, OH - EIR, 483, CO RESP 03/20/12
2013-6403	08/19/2013 09/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	JAMES R DEXTER MD, REDLANDS, CA - EIR, 483, CO RESP 08/08/12
2013-6404	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	FOREST RESEARCH INSTITUTE INC, JERSEY CITY, NJ - EIR, 483, CO RESP 02/14/12
2013-6405	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	COVENANT HEALTH CARE IRB, SAGINAW, MI - EIR, 483, CO RESP 05/02/12
2013-6406	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CELGENE CORP, SUMMIT, NJ - EIR, 483, CO RESP 09/12/12
2013-6407	08/19/2013 09/17/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	EMD SERONO INC, ROCKLAND, MA - EIR, 483, CO RESP 08/21/12
2013-6408	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	BELLIN HEALTH CORPATE IRB, GREEN BAY, WI - EIR, 483, CO RESP 07-25/12
2013-6409	08/19/2013 09/17/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	KVK TECH INC, NEWTOWN, PA - EIR, 483, CO RESP 09/17/12
2013-6410	08/19/2013 09/17/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	MCKESSON, SCOTTSDALE, AZ - EIR, 483, CO RESP 06/21/12
2013-6411	08/19/2013 09/17/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	NATUREPLEX LLC, OLIVE BRANCH, MS - EIR, 483, CO RESP 08/28/12
2013-6412	08/19/2013	FDA/OGROP/ORA/SW-FO/DAL-	WALTER E CHALKLEY	ISO-TEX DIAGNOTIS, INC, FRIENDSWOOD, TX - EIR, 483,

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	09/17/2013	DO/DAL-CB/	THOMSON REUTERS	CO RESP 09/07/12
2013-6413	08/19/2013 09/17/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	TOLMAR INC, FORT COLLINS, CO - EIR, 483, CO RESP 09/07/12
2013-6414	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	VERSAPHARM INC, MARIETTA, GA - EIR, 483, CO RESP 06/08/12
2013-6415	08/19/2013 09/17/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	SAGFENT PHARMACEUTICALS INC, SCHAUMBURG, IL - EIR, 483, CO RESP 05/11/12
2013-6416	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HAWTHORN PHARMACEUTICALS INC, MADISON, MS - EIR, 483, CO RESP 02/15/12
2013-6417	08/19/2013 09/17/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	EKR HOLDINGS INC, BEDMINSTER, NJ - EIR, 483, CO RESP 04/16/12
2013-6418	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ZACHARY K SEGAL MD, MIAMI, FL - EIR, 483S, CO RESP 03/02/12
2013-6419	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALVARO H SKUPIN MD, MIAMI, FL - EIR, 483, CO RESP 08/29/12
2013-6420	08/19/2013 09/17/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALABAMA ORGAN CENTER, MOBILE, AL - EIR, 483, CO RESP 03/05/13
2013-6421	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5780, 5772, 5398, 5350, 4938, 4244
2013-6422	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5988, 4423, 4084
2013-6423	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3708, 4460
2013-6424	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5780, 5772, 5398, 5350, 4938, 4244
2013-6425	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-4979, 5813

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2013-6426	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3907
2013-6427	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3606, 3607, 4045, 4081
2013-6428	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5761, 5481, 4056, 3984, 3969
2013-6429	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-3846
2013-6430	08/20/2013 09/18/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	ELLIOT FAVUS, MD FAVUS INSTITUTIONAL RESEARCH LLC	2013-5642, 5585, 5349, 5347, 5331, 5323
2013-6431	08/20/2013 09/18/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELAINE S. WALLER, PharmD, MBA SEATTLE GENETICS INC	ADCETRIS (BRENTUXIMAB VEDOTIN) - ISRS 8813991, 8816974, 8486800 ETC
2013-6432	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M. HOFFMEISTER WILSON SOSINI GOODRICH & ROSATI	RANBAXY - ESOMEPRAZOLE MAGNESIUM ANDA 77-830 APRVL, 483 1/12/12 TO 8/9/13
2013-6433	08/20/2013 09/18/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN., ROBERT	CALPOL SIX PLUS,CALPOL PAED SUSPENSION; CALPOL S/FREE SUSPENSION - FAERS 1969 TO PRESENT
2013-6434	08/20/2013 09/18/2013	ORA/ ORA/ FDA/OMPT/CDRH/OCER/DFOI/	DIANE K. SHAW SHAW AND ASSOCIATES	DEPUY - AML HIP REPLACEMENT STEM DVC CMLPNTS, PAST EIGHT YRS
2013-6435	08/20/2013 09/18/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	GAITHER, CHARLES .	MODERN HEALTH LABORATORIES INC, CULVER CITY,CA - EIR

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2013-6436	08/20/2013 09/18/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	COLLEEN GRACE DONOFRIO BABST CALLAD CLEMENTS ET AL	GILES CHEMICAL, WAYNESVILLE, NC - CORR, EIR 8/1-2/12
2013-6437	08/20/2013 09/18/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBIN WINCHESTER KESSLERTOPAZ MELTZERCHECK LLP	DCK FDA-2006-P-0007 - RECS; VIROPHARMA INC - SUPPLEMENTAL NDA 50-606/S028 MTG MINS, TRANS, CORR
2013-6438	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELENA HOWELL HOGAN LOVELLS LLP	AGLIA SPECIALITIES PRIVATE LTD, INDIA - 483, EIR 2012 TO 2013
2013-6439	08/20/2013 09/18/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT FDA-2007-D-0362
2013-6440	08/20/2013 09/18/2013	FDA/OF/CFSAN/OCD/EOS/	JEFFREY H. SCHULTZ DRISCOLL FIRM PC	SIMPLY THICK LLC - RECALL, LBLG, WARNINGS 5/11 AND 12/11
2013-6441	08/20/2013 09/18/2013	FDA/OMPT/CTP/OD/	MARC J SCHEINESON ASLTON & BIRD LLP	SUBSTANTIAL EQUIVALENCE (SE) PROVISIONAL RPT RESP LTRS, ADVICE/INFORMATION LTRS, WITHDRAWAL LTRS, ETC 3/11
2013-6442	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	PHARMACIA AND UPJOHN -DEPO - TESTOSTERONE (TESTOSTERONE CYPIONATE) ANDA 85-635 SBA
2013-6443	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	PHARMACIA (METHYLPREDNISOLONE ACETATE) NDA 11-757 SBA
2013-6444	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	PHARMACIA (DEPO PROVERA) NDA 20-246
2013-6445	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	MERCK SHARP DOHME (CELESTONESOLUSPAN) NDA 14-602 SBA

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6446	08/20/2013 09/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANURAG PATEL, Ph.D. DR REDDY'S LABORATORIES INC	WARNER CHILCOTT US - ESTRACE ANDA 86-069 SBA
2013-6447	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5222 - REQUEST LETTER
2013-6448	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5255 - REQUEST LETTER
2013-6449	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5336 - REQUEST LETTER
2013-6450	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5320, 2013-5322, 13-5328 ETC REQUEST LETTER ONLY
2013-6451	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5084 - REQUEST LETTER
2013-6452	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5397 - REQUEST LETTER
2013-6453	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5515 - REQUEST LETTER
2013-6454	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) 267-305-7723 MERCK & CO., INC.	2013-5884 - REQUEST LETTER
2013-6455	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	INDIVIDUAL RECS
2013-6456	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	ANDA 090168 SBA

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2013-6457	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Mathew Pexa LAKE REGION MEDICAL	K102588
2013-6458	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	SBA ANDA:090294
2013-6459	08/21/2013 09/19/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Robert Behrer Koster Keunen, Inc.	COMPLAINT 128467
2013-6460	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Janica Alvarez Janica Alvarez	K950531, K020518, K081932
2013-6461	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5209
2013-6462	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ethan Hoffmann Sage Therapeutics	PHASE 4 COMMITMENTS FOR DEXMEDETOMIDINE
2013-6463	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 200603 S 010, 011
2013-6464	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	James McNally Velocity Diagnostics	K021317
2013-6465	08/21/2013 09/19/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 203263
2013-6466	08/21/2013 09/19/2013	CVM/OCD/	Sandy O'Kelley Merial Limited	AGRI-MECTIN PLUS CLURSULON - FOIA SUMMARY
2013-6467	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Corinne Regnier BAXTER HEALTHCARE	K832285

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2013-6468	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 8/12/2013 - 8/16/2013
2013-6469	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Sandy Chon Johns Hopkins University School of Medicine - Center for TB Research	APPROVAL LETTER HABITROL
2013-6470	08/21/2013 09/19/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	METHODOLOGY FOR QUANTITATIVE RISK ASSESSMENT FOR GRANDFATHERED TOBACCO PRODUCTS
2013-6471	08/21/2013 09/19/2013	CVM/OCD/	P.J. Huffstutter THOMSON REUTERS	ZILPATEROL - AERS
2013-6472	08/21/2013 09/19/2013	FDA/OGROP/ORACE-FO/BLT- DO/BLT-CB/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	PARI RESPIRATORY EQUIPMENT, INC, MIDLOTHIAN, VA - EIR 2008 TO PRESENT
2013-6473	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Eagle VANDERBILT UNIVERSITY	K110266
2013-6474	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	ANDA 80439 S 000
2013-6475	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GENE. E. MYERS, M.D. F.A.C.C. FLORIDA CARDIAC AND VASCULAR CONSULTANTS	PROTONIX (PANTOPRAZOLE) - AERS
2013-6476	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BOEHRINGER-INGELHEIM PHARM GMBH AND CO KG - 483
2013-6477	08/21/2013 09/19/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 103705 S 5230
2013-6478	08/21/2013	FDA/OGROP/ORACE-FO/KAN- DO/KAN-CB/	Chris Patullo	FLEMING & CO PHARMACEUTICALS - EXHIBITS 7, 8, 12, 13, 14, 26

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	09/19/2013		Long Pharmaceuticals, LLC	
2013-6479	08/21/2013 09/19/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	BRISTOL-MYERS SQUIBB, PRINCETON, NJ 12/28/11-1/27/12; PPD DEVELOPMENT, MORRISVILLE, NC 3/12-16/12; WILLIAM KUFS, SARATOGA, NY 2/9-24/12, ETC - EIRS, 483S, CORR, ETC
2013-6480	08/21/2013 09/19/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	NOVARTIS PHARMACEUTICALS CORP (NPC), EAST HANOVER, NJ - EIR, 483, CORR, ETC 6/3-5/13
2013-6481	08/21/2013 09/19/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	DR BRUCE ITELD MD, LOUISIANA HEART CENTER, SLIDELL, LA - EIR, 483, CORR, ETC 4/9-19/13
2013-6482	08/21/2013 09/19/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	WAYNE SADOWSKI NOVARTIS PHARMACEUTICALS CORP	DR DAVID MARGOLIN, FRESNO, CA 3/6-20/13; DR JOSHUA SHUA-HAIM, MANCHESTER, NJ 3/5-29/13 - EIR, 483, CORR, ETC
2013-6483	08/21/2013 09/19/2013	FDA/OF/CFSAN/OCD/EOS/	FRAN SILVERMAN TRUTH IN ADVERTISING INC	VERMA NUTRITION CO - VERVE, VERVE BOLD, VERVE ZERO SUGAR, ETC CAERS
2013-6484	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANNA MCCUTCHEN RYMED TECHNOLOGIES INC	VITAPATCH CATHETER SECUREMENT K896046
2013-6485	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMIE YIEH ABBOTT POINT OF CARE INC	I-STAT CELITE ACT CARTRIDGE K992571; I-STAT KAOLIN ACT CARTRIDGE K023582
2013-6486	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN MEDICAL SYSTEMS INC - K100807 REVIEWER NOTES, TELECONFERENCE MINS
2013-6487	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN MEDICAL SYSTEMS INC - K082677 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2013-6488	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN MEDICAL SYSTEMS INC - K082730 REVIEWER DECISION NOTES, TELECONFERENCE MINS
2013-6489	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	STEPHEN T FOWLER REED SMITH LLP	AMERICAN SYSTEMS INC - K071902 REVIEWER DECISION NOTES, TELECONFERENCE MINS

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2013-6490	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9101
2013-6491	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-9103
2013-6492	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2009-1632
2013-6493	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-118
2013-6494	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2013-1273
2013-6495	08/21/2013 09/19/2013	FDA/OC/OES/DFOI/	BRODY MULLINS WALL STREET JOURNAL	2012-5882
2013-6496	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NANCY GALLO HOME DIALYSIS PLUS (HD+)	NIPRO SET-SLIMLINE BLOOD TUBING SET WITH TRANSDUCER PROTECTORS AND PRMING SET K112628
2013-6497	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	NANCY GALLO HOME DIALYSIS PLUS (HD+)	NXSTAGE - BLOOD TUBING SET WITH PRE-ATTACHED DIALYZER K113023
2013-6498	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	INFOPIA CO LTD - GLUNEO BLOOD GLUCOSE MONITORING SYS, PROFESSIONAL BLOOD GLUCOSE MONITORING SYS K130181
2013-6499	08/21/2013 09/19/2013	FDA/OMPT/CDRH/OCER/DFOI/	LIANE LAROCHELLE DEKA RESEARCH & DEVELOPMENT CORP	FRESENIUS MEDICAL CARE NORTH AMERICA - 2008K @HOME HEMODIALYSIS MACHINE K124035
2013-6500	08/21/2013 09/19/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	PATRICIA L REGENYE Celgene Corporation	CHARLES BIRBARA, CLIN PHARMACOLOGY STUDY GROUP, WORCESTER, MA - EIR, 483, CORR 3/12 TO PRESENT
2013-6501	08/21/2013 09/19/2013	FDA/OGROP/ORA/SW-FO/DEN- DO/DEN-CB/	PATRICIA L REGENYE Celgene Corporation	VINCENT HANSEN, CA ASSOC NORTHERN UTAH, OGDEN, UT - 483S 12/08 TO PRESENT
2013-6502	08/21/2013 09/19/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	PATRICIA L REGENYE Celgene Corporation	JEFFREY SOSMAN, VANDERBILT UNIV MEDICAL CENTER, NASHVILLE, TN - 483S 9/10 TO PRESENT
2013-6503	08/21/2013 09/19/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	PATRICIA L REGENYE Celgene Corporation	STEPHEN BOOKBINDER, OCALA RHEUMATOLOGY RESEARCH CENTER, OCALA, FL - 483S 5/09 TO PRESENT
2013-6504	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Charles F. Owen Willowcroft Pharm Inc	CROMOLYN SODIUM - DMF

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2013-6505	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jameel Husain Fresenius Kabi USA, LLC	DSM FINE CHEMICALS, LINZ, AUSTRIA - EIR
2013-6506	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	IAVI IAVI	ITR LABORATORIES, CA NADA - EIR, 483, RESPONSE 01/01/2008 - 12/31/2008
2013-6507	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vikram Deswal East Bridge Capital Management Limited	WOCKHARDT, INDIA - 483 (07/15/2013 - 08/15/2013)
2013-6508	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Cathy Shachaf Orlucent	K014018
2013-6509	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Costello Gawi, LLC	ARCTIC EASE PMA
2013-6510	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mahidhar Chinta Micro Labs USA, Inc	NDA 021485
2013-6511	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130315
2013-6512	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	William Sietsema Sietsema, William	NDA 021660
2013-6513	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas P. Stewart Industrial Water Solutions, Inc.	SHARPS AWAY VERTICAL DROP LID-3 GALLON 510K
2013-6514	08/22/2013 09/20/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	INTUITIVE SURGICAL - RECS RE PRESS RELEASE, WARNING LETTER, MEDSUN ETC
2013-6515	08/22/2013	FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH	ANDA 203-399 - ROUTING SHEET

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	09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FARUQI & FARUQI LLP	
2013-6516	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	A LUKE SMITH FARUQI & FARUQI LLP	ANDA 203-399 APRVL LTR
2013-6517	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDRENE HERON ROCHE DIAGNOSTICS OPERATIONS	INPECCO-ABBOTT - ANALYZER K121012
2013-6518	08/22/2013 09/20/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/ FDA/OMPT/CDRH/OCER/DFOI/	LOREN LARKIN SAC CAPITAL ADVISORS LP	WRIGHT MEDICAL - AUGMENT NON-APPROVABLE LTR 8/13
2013-6519	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	REO TANSIMA MD HOSPITAL FOR SICK CHILDREN	VALPROIC ACID; VALPROATE; SODIUM VALPROATE - WARNING LTRS, SAFETY RECS, ALERTS SINCE 2/78
2013-6520	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SABRINA BOODHAN HOSPITAL FOR SICK CHILDREN	CEFRIAXONE, HEMOLYTIC ANEMIA - AERS
2013-6521	08/22/2013 09/20/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	Doe J	EPINEPHRINE BITATRATE - NDA 16-126 APRV PKG
2013-6522	08/22/2013 09/20/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	SIDHARTHA SINGH BRIAR MEADS CAPITAL LLC	PROTICA INC, WHITEHALL, PA - EIRS, 483S 8/27/12, 3/26/13
2013-6523	08/22/2013 09/20/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Doe J	QQTECH RED LASER POINTER PEN - SPL 694073 LAB RPT FINDINGS

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		FDA/OC/OES/DFOI/		
2013-6524	08/22/2013 09/20/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DE MATOS, JUSTIN A	M.G.L.A. CONTROLLED SUBSTANCES - REGULATIONS, ESTABLISHMENT, SCHEDULING, ETC
2013-6525	08/22/2013 09/20/2013	FDA/OC/OES/DDM/	BRODER, JILL	LIST OF CHRONOLOGICAL PETITIONS 1/97 TO 8/13
2013-6526	08/22/2013 09/20/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	Doe J	SIMPLY THICK LLC - THICKENING GEL PRODS RECALL, AERS, WARNINGS, ETC
2013-6527	08/22/2013 09/20/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	HEALTHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	CADMIUM CHOCOLATE - SPL 814896 SAFETY ASSESSMENT ATTACHMENTS, EXHIBITS
2013-6528	08/22/2013 09/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Doe J	INDIVIDUAL RECS 09/15/07 TO PRESENT (CERTIFIED)
2013-6529	08/22/2013 09/20/2013	FDA/OF/CFSAN/OCD/EOS/	EMILY K STUNK AKIN GUMP ET AL	AMERICAN FROZON FOOD INSTITUTE, ETC - NUTRIENT DATABASES SUBMISSIONS 1998, 1999
2013-6530	08/22/2013 09/20/2013	FDA/OF/CFSAN/OCD/EOS/	K&L GATES	FCN 295
2013-6531	08/22/2013 09/20/2013	ORA/ ORA/	ROGER FARMER NATIONAL TREASURY EMPLOYEES UNION	SWR EMPLOYEES - EPISODIC, RECURRING FWAPS, COMPLIANCE OFFICERS
2013-6532	08/22/2013 09/20/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MELANIE COURTOT TERRY FOX LABORATORY BCCRC	ANAPHYLAXIS;GUILLAIN BARRE SYNDROME - VAERS
2013-6533	08/22/2013 09/20/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	FAP 3A4801
2013-6534	08/22/2013 09/20/2013	FDA/OC/OES/DDM/	MARILYN WHITNEY COVINGTON & BURLING LLP	DKT FDA-2013-P-0148
2013-6535	08/22/2013 09/20/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N. BLUE, II ZETETIC INC	3MUS REDDOT ELECTRODE; 3M MICROPORE TAPE; 3M STERI STRIP ETC ENTRY NO AV3-0039844-1

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2013-6536	08/22/2013 09/20/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	DOUGLAS N. BLUE, II ZETETIC INC	NAIL POLISH; SHAMPOO - ENTRY NO M76-2038381-2
2013-6537	08/22/2013 09/20/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Doe J	CANNED MACKEREL ENTRY UPS-8050920-4, UPS-8052031-8 TEST RESULTS
2013-6538	08/22/2013 09/20/2013	FDA/OC/OES/DDM/	LAUREN FARRUGGIA Hyman, Phelps and McNamara	DKT FDA-2013-P-0148
2013-6539	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961387
2013-6540	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961386
2013-6541	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961384
2013-6542	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961383
2013-6543	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961382
2013-6544	08/22/2013 09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRAUSER DMD, JACK	K961381
2013-6545	08/23/2013 09/23/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Kimberly Viergever RIETZ LAW FIRM LLC	STRYKER REJUVENATE, ABG II MODULAR NECK HIP STEM - RECALL RECS
2013-6546	08/23/2013 09/23/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Alyssa Pagel Pagel, Alyssa	CONAGRA FOODS - EIR 01/01/2012 - 08/22/2013

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		FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/		
2013-6547	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lance Caughfield Kelsoe, Khoury, Rogers, Caughfield & Clark, PC	K830004 SUMMARY
2013-6548	08/23/2013 09/23/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO STATUS DETERMINATION
2013-6549	08/23/2013 09/23/2013	FDA/OGROP/ORASW-FO/SAN-DO/SAN-CB/	Brian Sims Indiana Botanic Gardens, Inc.	ASI MARKETING LLC - 483, EIR 07/01/2010 - 06/30/2011
2013-6550	08/23/2013 09/23/2013	FDA/OF/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC.	FCN 692
2013-6551	08/23/2013 09/23/2013	FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/ FDA/OMPT/CDER/ORDIDP/	Priya Dosanjh REPRIEVE	PENTOBARBITAL SODIUM POWDER IMPORTS 01/01/2013 - 08/21/2013
2013-6552	08/23/2013 09/23/2013	CVM/OCD/	Chris Ramezanpour BIODIMENSIONS RENEWABLE OILS	CVM LETTER OF NO OBJECTION TO THE NC DEPT OF AGRICULTURE FOR RAPESEED MEAL TO BE USED AS A FEEDSTUFF FOR SPECIFIC LIVESTOCK SPECIES
2013-6553	08/23/2013 09/23/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	b. burgess BURGESS, BERNIE	FDA FUNDING RECS FOR INSPECTION 3004927371 JANUARY 2005
2013-6554	08/23/2013 09/23/2013	FDA/OF/CFSAN/OCD/EOS/	John Hilgren ECOLAB INC	8B4076
2013-6555	08/23/2013 09/23/2013	ORA/ORM/ ORA/ORM/	Merle Zimmermann AMERICAN HERBAL PRODUCTS ASSOCIATION	LIST OF GMP INSPECTIONS FOR COMPLIANCE WITH 21 CFR Part 111 05/01/2012 - 07/31/2013
2013-6556	08/23/2013 09/23/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	Sandy O'Kelley Merial Limited	SUSAN BAKER DVM, WEST PALM BEACH, FL; BILL CAMPAIGNE DVM, SEGUIN, TX, CALVERT LABORATORIES, SCOTT TOWNSHIP, PA ETC - EIR
2013-6557	08/23/2013 09/23/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DFOI/	Jeffrey Gardner Jeffrey Gardner	HERBALIFE PRODUCTS - AERS 01/01/2008 - 08/21/2013
2013-6558	08/23/2013	FDA/OF/CFSAN/OCD/EOS/	Katherine Peralta	ENERGY DRINKS - AERS

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	09/23/2013		Northwestern University	
2013-6559	08/23/2013 09/23/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Dana Hayden Siegfried USA, LLC RA Manager Siegfried USA, LLC	MINUTES OF MEETING BETWEEN SIEGFRIED USA LLC AND NEW JERSEY DISTRICT OFFICE
2013-6560	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Martha Raskin, Paralegal Rivkin Radler LLP	NDA 019839 - APPROVAL RECS
2013-6561	08/23/2013 09/23/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lynn Shepler LTS & Associates /LYNN SHEPLER, MD JD	CORR BETWEEN FDA AND CDC RE LYME DISEASE OR BORRELLA BURGDORFERI 01/01/1977 - 08/19/2013
2013-6562	08/23/2013 09/23/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	CHANTELS BAKERY Denise Pender	CHANTELS BAKERY, STERLING,VA - RECS RE 7/3/13 INSPECTION, PHOTOS
2013-6563	08/23/2013 09/24/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ ORA/OCI/ ORA/OCI/	CINDI BRADEN Hickey Law Firm	TREN XTREME, AMERICAN CELLULAR LABS, MAURICE SANDOVAL, ETC - LAB RESULTS, WARNING LTRS, INVESTIGATION RECS, ETC
2013-6564	08/23/2013 09/23/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John Zhao Ameri-Asian Trading Dev., Inc.	SAMPLE SLIDES
2013-6565	08/23/2013	FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway	OGD MONTHLY STATISTICAL REPORT JULY 2013

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	09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LACHMAN CONSULTANT SERVICES, INC.	
2013-6566	08/23/2013 09/23/2013	FDA/OF/CFSAN/OCD/EOS/	JOHN VENADOS Herbalife International of America, Inc.	HERBALIFE PRODS - CAERS 1/10 TO PRESENT
2013-6567	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDRH/OCER/DFOI/	WANSING, HALEY	PIP AMERICA, PIP USA - BREAST IMPLANTS MODELS 99202, 97254 RECS PRIOR TO 2000
2013-6568	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	S MICHAEL SHARP PHD REGULATORY CONSULTING LTD	SIS WOUND DRESSING K973170
2013-6569	08/23/2013 09/23/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ CVM/OCD/ FDA/OF/CFSAN/OCD/EOS/	HEATHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	STATE GARDEN INC, CHELSEA, MA - RECS 10/12 TO 1/13
2013-6570	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROBERT E KILEY DANAHER LAGNESE PC	ZYLOPRIM (ALLOPURINOL) - WARNINGS, LBLG, AERS, ETC 5/10
2013-6571	08/23/2013 09/23/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	BELVIQ (LORCASERIN) - AERS
2013-6572	08/23/2013 09/23/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHRISTOPHER HENDEL CONSUMER REPORTS	QSYMIA (PHENTERMINE, TOPIRAMATE) - AERS
2013-6573	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	ERYTHROPED SUSPENSION, ERYTHROPED FORTE SF SUSPENSION - AERS 1969 TO 2013
2013-6574	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DETOMA X0415531, GARY	LUNESTA - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6575	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	BRENDA M GARTZ ELI LILLY & CO	DOTTIKON EXCLUSIVE SYNTHESIS AG, DOTTIKON, SWITZERLAND - EIR 9/28/12
2013-6576	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	S MICHAEL SHARP PHD REGULATORY CONSULTING LTD	BRIDGE EXTRACELLULAR COLLAGEN MATRIX WOUND DRESSING K122502
2013-6577	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	S MICHAEL SHARP PHD REGULATORY CONSULTING LTD	LTM WOUND DRESSING K082103
2013-6578	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Matt Strassner Powers Equity Holdings	K800839
2013-6579	08/23/2013 09/23/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Grady Ormond PHARMASYS	UNIVERSITY OF MIAMI CANCER RESEARCH CENTER - 483
2013-6580	08/23/2013 09/23/2013	FDA/OC/OES/DDM/	CARLA SCARMAZZI KING & SPALDING	DKT 2007-D-0369
2013-6581	08/23/2013 09/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	Reza Davani Janet Jenner & Suggs LLC	MASIMO CORPORATION, IRVINE, CA - FEB 2011 INSPECTION RECS; K111403, K120070
2013-6582	08/23/2013 09/23/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	DANIEL R. SULLIVAN GENTRY LOCKE ET AL	NEW ENGLAN COMPOUNDING CENTER - 483 10/26/12 (CERTIFIED)
2013-6583	08/23/2013 09/23/2013	FDA/OC/OES/DFOI/	ANDREW HACK, MD PhD MILLENNIUM MANAGEMENT LLC	2013-4021, 4384, 4419, 4421, 4469, 4957 ETC
2013-6584	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID G. ADAMS VENABLE LLP	EPINEPHRINE BITARTRATE NDA 16-126 - APRVL
2013-6585	08/23/2013 09/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E. CHALKLEY THOMSON REUTERS	PHARMACIA & UPJOHN - ZYVOX NDA 21-131/001; 21- 121/015; 21-131/016
2013-6586	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Skertic Mark Skertic	CORR BETWEEN FDA AND RAJENDRA KUMAR RE RANBAXY 04/01/2004 - 06/01/2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/		
2013-6587	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	Mark Skertic Mark Skertic	CORR BETWEEN FDA AND JAYADEEP DESHMUKH RE RANBAXY 04/01/2004 - 06/01/2013
2013-6588	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/OCI/ ORA/OCI/	Mark Skertic Mark Skertic	CORR BETWEEN FDA AND DINESH THAKUR RE RANBAXY 04/01/2004 - 06/01/2013
2013-6589	08/26/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Shalin Jani Aerie Pharmaceuticals, Inc.	CAYMAN CHEMICAL COMPANY, ANN ARBOR, MI; BIO-CONCEPT LABORATORIES, SALEM, NH; -CATALENT PHARMA SOLUTIONS, PHILADELPHIA, PA ETC - EIR LAST FIVE YEARS
2013-6590	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LYNN SHEPLER LTS & Associates /LYNN SHEPLER, MD JD	LYME DISEASE RECS RE BORRELIOSIS BURGDORFERI, ALLEN C STEERE, GARY WORMSER ETC 01/01/1985 - 08/19/2013
2013-6591	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Deborah Lavoie Grayeski M SQUARED ASSOCIATES INC	LISTING OIF ALL PRIOR ORTHOPEDIC APPLICATIONS CITING SECTION 216 OF FDAMA AND AGENCY DISPOSITION
2013-6592	08/26/2013 09/24/2013	FDA/OF/CFSAN/OCD/EOS/	Susan G. Etheridge, Esq. Susan G. Etheridge, P.A.	MITRAGYNA SPECIOSA - CLINICAL OR PRECLINICAL STUDIES
2013-6593	08/26/2013 09/24/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Reza Davani Janet Jenner & Suggs LLC	MASIMO CORPORATION, IRVINE, CA - INSPECTION RECS; K111403; K120070 ETC

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		FDA/OMPT/CDRH/OCER/DFOI/		
2013-6594	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OF/CFSAN/OCD/EOS/	Gabriela Steier CENTER FOR FOOD SAFETY	ALL RECS RE PRESENCE AND DEVELOPMENT OF GE ORANGES
2013-6595	08/26/2013 09/24/2013	FDA/OC/OES/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Lynn Shepler LTS & Associates /LYNN SHEPLER, MD JD	LYME DISEASE RECS RE BORRELIOSIS BURGDOFFER, ALLEN C STEERE, GARY WORMSER ETC 08/01/1977 - 01/01/1985
2013-6596	08/26/2013 09/24/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/ ORA/ORO/DFS/ ORA/ORO/DFS/ FDA/OGROP/ORA/ORO/DIOP/	Thomas Uebel Thomas Uebel	FOOD FROM TAIWAN - QUANTITY OF DEHP AND MALEIC ACID FOUND, ANALYTIC METHODS, DETECTION LIMIT, ETC
2013-6597	08/26/2013 09/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Stephen Telfer E Ink Corporation	FLUOROQUINOLONE ANTIBIOTICS - AERS BY STATE 01/01/1987 - 01/01/2013
2013-6598	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Neil Camera Laser Therapeutics, Inc.	K030622
2013-6599	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	LYNN SHEPLER LTS & Associates /LYNN SHEPLER, MD JD	UNCOMPLETED FORMS THAT A FIRM WOULD COMPLETE FOR APPLICATION FOR VACCINE
2013-6600	08/26/2013 09/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Oliver McKinley Resources, Inc.	LIST OF REGISTERED FOREIGN MANUFACTURERS OF ACTIVE PHARMACEUTICAL INGREDIENTS 01/01/2013 - 08/23/2013
2013-6601	08/26/2013 09/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Oliver McKinley Resources, Inc.	LIST OF ALL REGISTERED FOREIGN MANUFACTURERS OF HYDROCORTISONE
2013-6602	08/26/2013 09/24/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	John Oliver McKinley Resources, Inc.	LIST OF ALL REGISTERED FOREIGN MANUFACTURERS OF MICONAZOLE NITRATE 01/01/2013 - 08/23/2013
2013-6603	08/26/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson	FCN 970

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	09/24/2013		FOI Services, Inc.	
2013-6604	08/26/2013 09/24/2013	FDA/OF/CFSAN/OCD/EOS/	JoNel Aleccia, health reporter MSNBC.COM	TAYLOR FARMS DE MEXICO - 483 07/01/2013 - 08/23/2013
2013-6605	08/26/2013 09/24/2013	FDA/OO/OHR/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	GDUFA HIRES FOR FY13
2013-6606	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Liz Pretzinger Rawls McNelis + Mitchell	INDIVIDUAL RECS
2013-6607	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	Harold Roy, CEO, Heeren Bros Inc HEEREN BROS INC	SAMPLE RESULTS
2013-6608	08/26/2013 09/24/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	sidney a lewis sidney a. lewis	LEGACY PHARMACEUTICAL PACKAGING, EARTH CITY, MO - 483, RESPONSE 04/01/2012 - 08/15/2013
2013-6609	08/26/2013 09/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 201635
2013-6610	08/26/2013 09/24/2013	FDA/OC/OES/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	ANNA MENEDJIAN The Sizemore Law Firm	JOHNSON & JOHNSON, INC MCNEIL CONSUMER HEALTHCARE CHILDRENS' MOTRIN - RECALL, LABELING, AERS ETC
2013-6611	08/26/2013 09/24/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	Rachel Johnson FOI Services, Inc.	NEUROSCIENCE - WARNING LETTER RECS
2013-6612	08/26/2013 09/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Pamela Vetter ALLOSOURCE	REQUEST FOR RECOMMENDATION SENT TO TISSUE REFERENCE GROUP RE FY 2013 UPDATE
2013-6613	08/26/2013 09/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	BOTOX - AERS

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2013-6614	08/26/2013 09/24/2013	OM/OSS/OPILS/FDAHO/	Peter Sachs Collopy UNIVERSITY OF PENNSYLVANIA	MYRON STOLAROFF, LSD RESEARCH, Mescaline ETC BY AMPEX CORPORATION 01/01/1956 - 12/31/1967
2013-6615	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	John Strouse JOHNS HOPKINS UNIVERSITY	CEFTRIAXONE - MEDWATCH RPTS
2013-6616	08/26/2013 09/24/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OO/OFBA/OAGS/	Alon Peled THE HEBREW UNIVERSITY OF JERUSALEM	FDA-NTIS AGREEMENT TO PUBLISH FOOD CODE 2009 DATABASE
2013-6617	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	ANNA MCCUTCHEN RYMED TECHNOLOGIES INC	VITAPATCH - K895920
2013-6618	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAN MARIE EBERTH UNIV OF SOUTH CAROLINA/COLLEGE OF EPIDEMIOLOGY & BIOSTATISTICS	MAMMOGRAPHY FACILITIES IN THE US - (CERTIFIED) NAME, INSP DATE, FACILITY, ETC 7/1/13
2013-6619	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MELISSA EGAN WATERS CORP	VITEK MS K124067 - DENOVO CLASSIFICATION
2013-6620	08/26/2013 09/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAWN HAAKE NUVASIVE INC	NUVASIVE INC, MEMPHIS, TN - EIR 11/11
2013-6621	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	DON J MIZERK HUSCH BLACKWELL LLP	PAR PHARMACEUTICAL INC - DONEPZIL HCL ANDA 202-542 APRVL LTR 7/24/13; MACLEODS PHARMACEUTICALS LTD - DONEPEZIL HCL ANDA 202-631 APRVL LTR 7/24/13; DR REDDY'S LABORATORIES INC - DONEPEZIL HCL ANDA 202-723 APRVL LTR 7/24/13
2013-6622	08/26/2013 09/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	RUTH S TURNER FRESENIUS MEDICAL CARE	ABBOTT LABS (FMC) - INPERSOL/DELFLUX SAFE LOCK NDA 18-379 SAFETY RPTS, LBLG, CORR, ETC
2013-6623	08/26/2013 10/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	XIAO, CHRIS	REGENERXX STEM CELL THERAPY - INVESTIGATION, RESP
2013-6624	08/26/2013 09/24/2013	FDA/OO/OFBA/OAGS/	LAUREN R SILVIS SIDLEY AUSTIN LLP	NATIONAL RESEARCH COUNCIL - HHSF22301031T
2013-6625	08/26/2013 09/24/2013	ORA/ ORA/	GARY C COOPER GARY C COOPER LAW OFC	PEI TEN FOOD CO LTD, TAOYUAN COUNTY, TAIWAN - IMPORT ALERT 99-19 ENTRY 9EH-0001727-9, 93H-0001693-3, 9EH-0001194-2 INTER-AGENCY OR INTRA-

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		FDA/OGROP/ORA/ORO/DIOP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/		AGENCY MEMO, LTRS
2013-6626	08/26/2013 09/24/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	Doe J	IMDICA INC - ENTRY #E8400752652 NOTICES FOR REQUEST OF INFORMATION (CF28), NOTICES OF ACTION PROPOSED (CF29), CBP REDELIVER NOTICES (CF-4647), ETC
2013-6627	08/26/2013 09/24/2013	FDA/OC/OES/DFOI/	Paul Wehling General Mills, Inc.	FDA BYLINES RELIABILITY REQUIREMENTS OF AOAC AND FOOD CODEX METHODS OF ANALYSIS ETC
2013-6628	08/27/2013 09/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Mary Faith Harty Harty, Mary Faith	RECS RE MISMATCHED LISTINGS OF TISSUE BANKS AT THE UNIVERSITY OF MIAMI
2013-6629	08/27/2013 09/25/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Mary Majer Wright Medical Technology, Inc.	DAVID KENT DEBOER, NASHVILLE, TN - EIR, 483 (01/31/2013 - 08/26/2013)
2013-6630	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-3989
2013-6631	08/27/2013 09/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Patrick Smith Franklin Law Group	APRIL 1984 DRUG BULLETIN SOURCE ADR HIGHLIGHT NO 83-12
2013-6632	08/27/2013 09/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ FDA/OC/OES/DFOI/	Alexandra Ajmo LIFE EXTENSION	XYMOGEN, ORLANDO, FL - EIR (08/26/2011 - 08/26/2013)
2013-6633	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KATHRYN E WHITE EPSTEIN BECKER & GREEN PC	2012-6877
2013-6634	08/27/2013 09/25/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	MOLINE, MAGGIE	ECLOSION KFT - EPFX BIOFEEDBACK DVCS INVESTIGATION, RESEARCH RECS
2013-6635	08/27/2013 09/25/2013	CVM/OCD/	KHUSHI K DESAI Earthjustice	AQUABOUNTY TECHNOLOGIES - AQUADVANTAGE GENETICALLY ENGINEERED (GE) SALMON APRVL RECS, BIOLOGICAL ASSESSMENT, CORR, ETC
2013-6636	08/27/2013 09/25/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ FDA/OGROP/ORA/SW- FO/SWID/SWID-CB/	BENJAMIN L ENGLAND ESQ BENJAMIN L ENGLAND & ASSOCIATES LLC	ENTRY #DC1-0108151-1 - INSP, DETETIONS, REFUSAL OF ENTRY, ETC
2013-6637	08/27/2013	FDA/OF/CFSAN/OCD/EOS/	CATHERINE R NIELSEN	BRIK PAK INC - HYDROGEN PEROXIDE SOL FCN, RVW

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	09/25/2013		Keller and Heckman LLP	MEMO
2013-6638	08/27/2013 09/25/2013	CVM/OCD/	TIM SCHWAB Food & Water Watch	AQUABOUNTY TECHNOLOGIES - AQUADVANTAGE GENETICALLY ENGINEERED SALMON NOAA RECS, CORR
2013-6639	08/27/2013 09/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	SHELLY S JOCK RALPH C JONES LAW OFCS	MDRS 8010047-2013-00141M 9610773-2013-00043
2013-6640	08/27/2013 09/25/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	SHELLY S JOCK RALPH C JONES LAW OFCS	OLYMPUS - SURGMASTER ELECTROSURGICAL UNIT (UES-40) RECALL NUMBER S-1277-2013 RECS
2013-6641	08/27/2013 09/25/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	FINNEY H-19359, STANLEY	METAZIPINE 2001-2004; TRILOPTAL 2003-2007; LAMACTIL 2009-2013 - AERS
2013-6642	08/27/2013 09/25/2013	FDA/OC/OES/DDM/	DOREEN FRANK ENVISAGE CONSULTING LLC	DKT 1978N-0021D, 1980N-0036
2013-6643	08/27/2013 09/25/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	RAMIL M FERNANDO BIOSCREEN TESTING SERVICES INC	AMA LABORATORIES INC, NEW YORK, NY - EIRS, 483S, WARNING LTRS, ETC LAST 5 YRS
2013-6644	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 7/29/13-8/2/13
2013-6645	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/5-9/13
2013-6646	08/27/2013 09/25/2013	ORA/ORM/ ORA/ORM/	GAIL LESSICK LACHMAN CONSULTANT SERVICES INC	DRUG COMPANIES, MEDICAL DVC MFRS, BIORESEARCH MONITORING (BIMO), ETC - DOMESTIC AND FOREIGN INSPS, 483S 6/1-30/13
2013-6647	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DOMINION GROUP INC	DAILY LOG 7/22-26/13
2013-6648	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/22-26/13
2013-6649	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/22-26/13
2013-6650	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	7/29/13-8/2/13

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2013-6651	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/5-9/13
2013-6652	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 7/29/13-8/2/13
2013-6653	08/27/2013 09/25/2013	FDA/OGROP/ORR/SW-FO/DEN-DO/DEN-CB/	GERARD RYAN BSC APTIV SOLUTIONS	DR LORA BARKE, DR TERESE I KASKE; RADIOLOGY IMAGING ASSOCIATES, ENGLEWOOD, CO; INVISON SALLY JOSE, GREENWOOD, CO - 483 2010
2013-6654	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/5-9/13
2013-6655	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/29/13-8/2/13
2013-6656	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/5-9/13
2013-6657	08/27/2013 09/25/2013	FDA/OGROP/ORR/PA-FO/SEA-DO/SEA-CB/	KELLI WASSGREN FRYE ELECTRONICS	FRYE ELECTRONICS, TIGARD, OR - EIR MOST RECENT
2013-6658	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 7/22-26/13
2013-6659	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	GLADYS TONKIN Center for Regulatory Services, Inc.	DAILY LOG 7/29/13-8/2/13
2013-6660	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	GLADYS TONKIN Center for Regulatory Services, Inc.	DAILY LOG 8/5-9/13
2013-6661	08/27/2013 09/25/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	BAYER, RANGE RICHARD D	ALLOGENIC WHOLE BLOOD AND APHRESIS RED BLOOD CELL DONORS - POST-DONATION FATALITY RPTS FY 2006 AND FY 2008
2013-6662	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/29/13-8/2/13
2013-6663	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/5-9/13
2013-6664	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 7/22-26/13
2013-6665	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/22-26/13

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2013-6666	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 7/29/13-8/2/13
2013-6667	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/5-9/13
2013-6668	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/22-26/13
2013-6669	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/22-26/13
2013-6670	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/5-9/13
2013-6671	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/29-8/2/13
2013-6672	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/5-9/13
2013-6673	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	DEBRA COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 7/29/13-8/2/13
2013-6674	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	GLADYS TONKIN Center for Regulatory Services, Inc.	DAILY LOG 7/22-26/13
2013-6675	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/5-9/13
2013-6676	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 7/29/13-8/2/13
2013-6677	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY LOG 7/29/13-8/2/13
2013-6678	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED OG 8/5/9/13
2013-6679	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	LAUREN BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 7/22-26/13
2013-6680	08/27/2013	FDA/OC/OES/DFOI/	LAUREN BARR	DAILY LOG 7/22-26/13

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	09/25/2013		JH BARR & ASSOCIATES LLC	
2013-6681	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 7/22-26/13
2013-6682	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 8/5-9/13
2013-6683	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 7/29/13-8/2/13
2013-6684	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 7/29/13-8/2/13
2013-6685	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 7/29/13-8/2/13
2013-6686	08/27/2013 09/25/2013	FDA/OC/OES/DDM/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	DKT 78N-0021
2013-6687	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-8110
2013-6688	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-4173
2013-6689	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Robert King FDA NEWS	FOIA REQUEST LOG 08/19/2013 - 08/23/2013
2013-6690	08/27/2013 09/25/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-5035
2013-6691	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Elizabeth Nunez CNN	CIPROFLOXACIN - AERS
2013-6692	08/28/2013 09/26/2013	FDA/OMPT/OSMP/OOPD/	H. Greg Thomas codaDOSE, Inc	EPANED ORPHAN DRUG DESIGNATION REQUEST FOR TREATMENT OF HYPERTENSION IN PEDIATRIC PATIENTS
2013-6693	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Van Langley Sandwick ORA, Inc	NDA 020613 S000

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6694	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Janell Colley Tornier Inc.	K920666, K933361, K951740 ETC
2013-6695	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Daniel O'Brien The Law Office of Daniel O'Brien	INCIVEK - ADVERSE EVENT, EXHIBITS, ETC
2013-6696	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dominick DiPaolo DiPaolo, Dominick	WOCKHARDT LIMITED, INDIA - EIR 03/18/2013 - 07/18/2013
2013-6697	08/28/2013 09/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	shin kang WELLS FARGO	VIROPHARMA/SANQUIN - 483, EIR, REPSONSE 08/01/2013 - 08/26/2013
2013-6698	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 21036 S 008
2013-6699	08/28/2013 09/26/2013	ORA/ ORA/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	MICHAEL CHASEY 483, EIR JULY 1, 2009 TO PRESENT
2013-6700	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Nunez CNN	MOXIFLOXACIN - AERS
2013-6701	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL J CUSHING PHD NURON BIOTECH	BLA 103628/5191, 103628/5189
2013-6702	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DANIEL J CUSHING PHD NURON BIOTECH	BLA 103780/5121
2013-6703	08/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Steve Pardue	K101346

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	09/26/2013		Elevate Oral Care	
2013-6704	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Guy C Ruble Eli Lilly and Company, Inc.	NDA 022334/S-016
2013-6705	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sandy Lee B&H Consulting Services, Inc.	WOCKHARDT LIMITED, INDIA - 483 07/01/2013 - 07/31/2013
2013-6706	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRATTI, JOHN	LEVAQUIN - AERS 1997 TO PRESENT
2013-6707	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	TRADOREC XL 100, 200, 300 TABS - AERS 1969 TO PRESENT
2013-6708	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	GABRIEL LEOR COMBINED INNOVATIONS	HEALTHMATE INTERNATIONAL LLC, HI-DOW INERNTIONAL LLC - JQ-5C TECHNOLOGY DVC SPECIFICATIONS RELATED TO 510 APRVL, FDA FACILITY
2013-6709	08/28/2013 09/26/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN M ENGEL ENGEL NOVITT, LLP	ANTIBACTERIAL FLUOROQUINOLONE - LABEL CHANGES TO WARNING OF RISK FOR POSSIBILITY PERMANET NERVE DAMAGE
2013-6710	08/28/2013 09/26/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	GRAIG ROUSH ROCHLINE INDUSTRIES	GUY & O'NEILL INC, FREDONIA, WI - EIRS, 483S, COMM 12/12
2013-6711	08/28/2013 09/26/2013	FDA/OC/OES/DFOI/	HILLS, SARAH	NIH, PHS, OLAW, ETC - CUMMULATIVE PERSONNEL SALARY PER YEAR
2013-6712	08/28/2013 09/26/2013	FDA/OF/CFSAN/OCD/EOS/	WIMBUSH #SB-3584, RICHARD M	MONO & DIALYCERIDES FROM PORK INGREDIENTS; LIST OF PORT INGREDIENTS
2013-6713	08/28/2013 09/26/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	REEL, CHARLES	MEDICAL DEVICE KING, PHARMALOGICAL INC - BOTOX SPL RPT INVESTIGATION 5/19/13

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2013-6714	08/28/2013 09/26/2013	FDA/OC/OES/DDM/	SHARON DAVIS CROMWELL MOORING	DKT FDA-2013-P-0148
2013-6715	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Anita Fauchier, Executive Director, Regulatory Affairs Cempra Pharmaceuticals (Anita Fauchier)	WOCKHARDT, INDIA - 483 07/22/2013 - 07/31/2013
2013-6716	08/28/2013 09/26/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Joakim Aske not applicable	WOCKHARDT - 483 06/01/2013 - 08/27/2013
2013-6717	08/28/2013 09/26/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Doe J	INDIVIDUAL RECS
2013-6718	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/	Louis Marcoux ZELTIQ Aesthetics, Inc.	TRADE COMPLAINT RECS
2013-6719	08/28/2013 09/26/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	Susan Zolnier Zolnier, Susan	MANNKIND CORPORATION, DANBURY, CT - EIR 11/12/2009 - 12/04/2009
2013-6720	08/28/2013 09/26/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SUNFLOWER MEDICAL - REGISTRATION AND LISTING, GMP RECS, ADVERSE EVENTS
2013-6721	08/28/2013 09/26/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Anna Edney BLOOMBERG NEWS	RTI SURGICAL, MUSCULOSKELETAL TRANSPLANT FOUNDATION, SHIRE ETC - AERS
2013-6722	08/28/2013 09/26/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kevin Meder MC Biopharma/Kevin Meder	K061855
2013-6723	08/29/2013 09/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	LA TOYA SUTTON MANATT PHELPS & PHILLIPS LLP	NIX LICE TREATMENT, RID, LICE SHIELD, ETC - LACK OF EFFICACY RPTS
2013-6724	08/29/2013 09/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	ALEX C DAVIS JONES WARD PLC	ZIMMER - TRILOGY AB HIP DVC P040048 PRE-MARKET APRVL WITHDRAWAL
2013-6725	08/29/2013 09/27/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	B KRISTIAN RAMUSSEN CORY WATSON ET AL	FDA DRUG SAFETY COMMUNICATION: IMPORTANT SAFETY LABEL CHANGES TO CHOLESTEROL-LOWERING STATIN DRUGS 2/28/12; CLNCL TRIAL META-ANALYSES AND EPIDEMIOLOGICAL DATA

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2013-6726	08/29/2013 09/27/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MARK FORD ESQ FORD & FINNERTY LLC	ZEPPESSIS REPROCESSING LLC - MEDICAL SUCTION APPARATUS, MEDICAL MANIFOLDS/FILTERS, WARNING LTRS, ETC CORR 1/1/13
2013-6727	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	ANDREA L NORDLUND AMERICAN RED CROSS GREAT LAKES REGION	AMERICAN RED CROSS, LANSING, MI 3/3-20/08, 4/5-27/10; FLINT, MI 10/10/12, ETC - EIRS
2013-6728	08/29/2013 09/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	INDIVIDUAL RECS
2013-6729	08/29/2013 09/27/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	K MICHELLE VASSALLO LINCARE INC	BREWER MEDICAL SERVICES INC, AL - EIRS, 483S, WARNING LTRS, 1/05 TO PRESENT
2013-6730	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	K MICHELLE VASSALLO LINCARE INC	BLUE RIDGE RESPIRATORY AND MEDICAL EQUIPMENT SERVICES LLC, VA - EIRS, 483S, WARNING LTRS 1/05 TO PRESENT
2013-6731	08/29/2013 09/27/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	CORBETT, SUZANNE	FOOD VENDORS, ASHFIELD, MA - VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM STANDARDS RECS
2013-6732	08/29/2013 09/27/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	WALTIER E CHALKLEY THOMSON REUTERS	VISTAPHARM INC, LARGO, FL - EIR, 483, CO RESP 6/15/12
2013-6733	08/29/2013 09/27/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	WALTIER E CHALKLEY THOMSON REUTERS	STERI-PHARMA LLC, SYRACUSE, NY - EIR, 483, CO RESP 9/20/12
2013-6734	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTIER E CHALKLEY THOMSON REUTERS	PERRIGO HOLLAND INC, HOLLAND, MI - EIR, 483, CO RESP 8/24/12
2013-6735	08/29/2013 09/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTIER E CHALKLEY THOMSON REUTERS	LEK PHARMACEUTICALS, LIUBLJANA, SLOVENIA - EIR, 483, CO RESP 4/6/12
2013-6736	08/29/2013 09/27/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	WALTIER E CHALKLEY THOMSON REUTERS	GILEAD SCIENCES INC, FOSTER CITY, CA - EIR, 483, CO RESP 6/26/12
2013-6737	08/29/2013 09/27/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTIER E CHALKLEY THOMSON REUTERS	CODY LABORATORIES INC, CODY, WY - EIR, 483, CO RESP 10/12/12
2013-6738	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	WALTIER E CHALKLEY THOMSON REUTERS	ELORAC INC, VERNON HILLS, IL - EIR, 483, CO RESP 1/20/12

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2013-6739	08/29/2013 09/27/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTIER E CHALKLEY THOMSON REUTERS	JQC (HUAYIN) PHARMACEUTICAL CO LTD, HUAYIN CITY, CHINA - EIR, 483, CO RESP 1/24/13
2013-6740	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTIER E CHALKLEY THOMSON REUTERS	CELGENE CORP, SUMMIT, NJ - EIR, 483, CO RESP 7/30/12
2013-6741	08/29/2013 09/27/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	WALTIER E CHALKLEY THOMSON REUTERS	MID-CONTINENT PACKAGING INC, ENID, OK - EIR, 483, CO RESP 1/24/13
2013-6742	08/29/2013 09/27/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTIER E CHALKLEY THOMSON REUTERS	NGL NE LLP (SHORELINE COMPRESSED GAS), NORTH HAVEN, CT - EIR, 483, CO RESP 1/9/13
2013-6743	08/29/2013 09/27/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTIER E CHALKLEY THOMSON REUTERS	NORTH ATLANTIC MEDICAL SERVICE, LEOMINSTER, MA - EIR, 483, CO RESP 1/29/13
2013-6744	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	WALTIER E CHALKLEY THOMSON REUTERS	OHIO VALLEY MEDICAL GAS & SUPPLY, EVANSVILLE, IN - EIR, 483, CO RESP 1/31/13
2013-6745	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	WALTIER E CHALKLEY THOMSON REUTERS	PETNET SOLUTIONS INC, CHARLOTTESVILLE, VA - EIR, 483, CO RESP 2/19/13
2013-6746	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTIER E CHALKLEY THOMSON REUTERS	POWDERSIZE INC, QUAKERTOWN, PA - EIR, 483, CO RESP 2/26/13
2013-6747	08/29/2013 09/27/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTIER E CHALKLEY THOMSON REUTERS	SONAR PRODUCTS INC, CARLSTADT, NJ - EIR, 483, CO RESP 2/15/13
2013-6748	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-6515
2013-6749	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-8048
2013-6750	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-6452
2013-6751	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-7753
2013-6752	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-8026

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2013-6753	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-7611
2013-6754	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2011-6474
2013-6755	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-186
2013-6756	08/29/2013 09/27/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-205
2013-6757	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gwen Majors Majors, Gwen	K11277
2013-6758	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CARTER GOULD GOULD, CARTER	GATTEX - AERS
2013-6759	08/30/2013 09/30/2013	FDA/OF/CFSAN/OCD/EOS/	Dr. Erick DeWolf KANSAS STATE UNIVERSITY	LEVELS OF MYCOTOXIN DEOXYNIVALENOL IN WHEAT GRAIN AND FOOD PRODUCTS LAST TEN YEARS
2013-6760	08/30/2013 09/30/2013	FDA/OGROP/ORR/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	RAY'S INC - REGISTRATION AND LISTING, INSPECTION RECS, ADVERSE EVENTS
2013-6761	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Mark Prinz Registrar Corp	ELECTRONIC LIST OF DRUG DATA SUBMITTED TO FDA 06/01/2009 - 05/31/2013
2013-6762	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ali Bonakdar VIRGINIA COMMONWEALTH UNIVERSITY	ADVERSE EVENTS BY STATE
2013-6763	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tannista Banerjee AUBURN UNIVERSITY	IRB ASSOCIATE WITH NEW MOLECULAR ENTITIES APPROVED 07/01/1993 - 12/31/2005

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2013-6764	08/30/2013 09/30/2013	ORA/ ORA/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Mary Hancock Registrar Corp	182-0271232-1/1/1
2013-6765	08/30/2013 09/30/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Doe J	INDIVIDUAL RECS
2013-6766	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elizabeth Nunez CNN	LEVOFLOXACIN - AERS
2013-6767	08/30/2013 09/30/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Mary Emily Monroe McDowell Knight Roedder & Sledge, LLC	SIZewise Rentals - Registration and Listing, Inspection Recs, Adverse Events
2013-6768	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rivelino Montenegro Medovent GmbH	K002098
2013-6769	08/30/2013 09/30/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1177
2013-6770	08/30/2013 09/30/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1212
2013-6771	08/30/2013 09/30/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FCN 1213
2013-6772	08/30/2013 09/30/2013	CVM/OCD/	Chad Miller U.S. citizen	RACTOPAMINE, TYLOSIN - FDA SUPPORT FOR DEC 2009 STATEMENT RE ENVIRONMENTAL IMPACT ASSESSMENT
2013-6773	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020844 - APPROVAL PACKAGE
2013-6774	08/30/2013 09/30/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Allison J. Leonard Patino & Associates, P.A.	LANMAN KEMP & BARCLAY & CO - REVIEW OF LABELS FLORIDA WATER
2013-6775	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 017851 APPROVAL PACKAGE

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6776	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lawrence Biegelsen WELLS FARGO	CARDIOMEMS - RESPONSE TO WARNING LETTER
2013-6777	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 018029
2013-6778	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Fred Saulo Wilson Sonsini Goodrich & Rosati	ANDA 78-340 TENTATIVE APPROVAL LETTER
2013-6779	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-249
2013-6780	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-274
2013-6781	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-775
2013-6782	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-770
2013-6783	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-263
2013-6784	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-266
2013-6785	08/30/2013 09/30/2013	FDA/OF/CFSAN/OCD/EOS/	FOI Services, Inc.	FCN 939
2013-6786	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-761

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2013-6787	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-759
2013-6788	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-277
2013-6789	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-741
2013-6790	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-738
2013-6791	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-368
2013-6792	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-733
2013-6793	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-727
2013-6794	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-726
2013-6795	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-724
2013-6796	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Wurst STUDENT	K120188, K014108, K123217 ETC
2013-6797	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Evelyn Gittinger Gamma Medica, Inc.	MQSA CERTIFIED FACILITY LIST BY FACILITY TYPE
2013-6798	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Wagner Allianz	MTG MINUTES BETWEEN SAREPTA THERAPEUTICS AND FDA DIVISION OF NEUROLOGY PRODUCTS RE ETEPLIRSEN
2013-6799	08/30/2013	FDA/OMPT/CDER/ORP/DIDP/	Nancy Dougherty	4350738, 4360507, 6059993 ETC

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	09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SANOFI	
2013-6800	08/30/2013 09/30/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	McGuff Pharmaceuticals, Inc Kington Capital Management	MCGUFF PHARMACEUTICALS, SANTA ANA, CA - 483, EIR 09/01/2011 - 08/28/2013
2013-6801	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8566
2013-6802	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8185
2013-6803	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7928
2013-6804	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7753
2013-6805	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michael Lalonde Deshum Medical LLC	K121374
2013-6806	08/30/2013 09/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alan Katz BLOOMBERG NEWS	LIST OF DRUGS APPROVED WITH BLACK BOX WARNINGS, LIST OF DRUGS WITH BLACK BOX WARNING ADDED AFTER FIRST APPROVAL, LIST OF WORDING CHANGES ETC
2013-6807	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 010187
2013-6808	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K131870
2013-6809	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Shara Ambrosecchia G&W Laboratories Inc.	NDA 020700 - SBA

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2013-6810	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Quality Solutions and Support, LLC	K121920;
2013-6811	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Quality Solutions and Support, LLC	K113097
2013-6812	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Stephen Inglese Quality Solutions and Support, LLC	K122950
2013-6813	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7667
2013-6814	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-369
2013-6815	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-489
2013-6816	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7577
2013-6817	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-7094
2013-6818	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	PATHEON UK LIMITED, SWINDON, UK - EIR, 483, CO RESP 7/20/12
2013-6819	08/30/2013 09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	WALTER E CHALKLEY THOMSON REUTERS	GE HEALTHCARE AS, OSLO, NORWAY - EIR, 483, CO RESP 12/13/12
2013-6820	08/30/2013 09/30/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	MEDISCA INC, IRVING, TX - EIR, 483, CO RESP 1/26/12
2013-6821	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-6211
2013-6822	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-512

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2013-6823	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-6008
2013-6824	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-5215
2013-6825	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	GLAXO SMITH KLINE, COLLEGEVILLE, PA - EIR, 483, CO RESP 9/19/12
2013-6826	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-4825
2013-6827	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-2779
2013-6828	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-1491
2013-6829	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-589
2013-6830	08/30/2013 09/30/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-721
2013-6831	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, 483, CO RESP 3/18-22/13
2013-6832	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	SENTISS PHARMA PVT LTD, KHERA NIHLA VILLAGE, TEHSIL NALAGARH, INDIA 3/25/13, 4/3/13
2013-6833	08/30/2013 09/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	POSH CHEMICALS PVT LTD, HYDERABAD, INDIA - EIE, 483, CO RESP 3/3-8/13

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2013-6834	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LIFESERVE BLOOD CTR, DES MOINES, IA - EIR, 483, CO RESP 6/13-27/13
2013-6835	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	RELIABLE BIOPHARMACEUTICAL CORP, OVERLAND, MO - EIR, 483, CO RESP 4/27/12
2013-6836	08/30/2013 09/30/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	RHODES PHARMACEUTICALS LP, COVENTRY, RI - EIR, 483, CO RESP 3/21/12
2013-6837	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	THOMAS R WALTERS MD, AUSTIN, TX - EIR, 483, CO RESP 4/19/12
2013-6838	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	TRI MED SUPPLES INC, PLYMOUTH MTG, PA - EIR, 483, CO RESP 4/6/12
2013-6839	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	UPM PHARMACEUTICALS, BALTIMORE, MD - EIR, 483, CO RESP 11/13/12
2013-6840	08/30/2013 09/30/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	WESTWOOD LABORATORIES, AZUSA, CA - EIR, 483, CO RESP 4/11/12
2013-6841	08/30/2013 09/30/2013	FDA/OGROP/ORASE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	WYETH PHARMACEUTICAL CO, GUAYAMA, PR - EIR, 483, CO RESP 7/11/12
2013-6842	08/30/2013 09/30/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALLAY PHARMACEUTICALS LLC, HIALEAH, FL - EIR, 483, CO RESP 10/12/12
2013-6843	08/30/2013 09/30/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	PERNIX MANUFACTURING LLC, HOUSTON, TX - EIR, 483, CO RESP 1/12/12
2013-6844	08/30/2013 09/30/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	STERIS ISOMEDIX SERVICES, LIBERTYVILLE, IL - EIR, 483, CO RESP 1/29/13
2013-6845	08/30/2013 09/30/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	KENNETH E KRELL MD, IDAHO FALLS, ID - EIR, 483, CO RESP 7/27/13
2013-6846	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	INTAS PHARMACEUTICALS LTD, AHMEDABAD CITY, INDIA - EIR, 483, CO RESP 5/19/12
2013-6847	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WATER E CHALKLEY THOMSON REUTERS	DISHMAN PHARMACEUTICALS & CHEMICALS LTD - AHMEDABAD GUJARAT, INDIA 3/17/12

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2013-6848	08/30/2013 09/30/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	CBA RESEARCH INC, LEXINGTON, KY - EIR, 483, CO RESP 10/19/12
2013-6849	08/30/2013 09/30/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	BANNER PHARMACAPS INC, HIGH POINT, NC - EIR, 483, CO RESP 6/6/12
2013-6850	08/30/2013 09/30/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	ALAUNUS PHARMACEUTICAL LLC, FRAMINGHAM, MA - EIR, 483, CO RESP 11/16/12
2013-6851	08/30/2013 09/30/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	CAPE MEDICAL SUPPLY INC, SANDWICH, MA - EIR, 483, CO RESP 5/11/12
2013-6852	08/30/2013 09/30/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	GTX INC, MEMPHIS, TN - EIR, 483, CO RESP 7/19/12
2013-6853	08/30/2013 09/30/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIOCLINICA INC, NEWTOWN, PA - EIR, 483, CO RESP 3/7/12
2013-6854	08/30/2013 09/30/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	FRESENIUS KABI AG, BAD HOMBURG, GERMANY - EIR, 483, CO RESP 1/14-18/13
2013-6855	08/30/2013 09/30/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOSPITAL ESPANOL AUXILIO MUTUO DE PUERTO RICO INC IRB, SAN JUAN, PR - EIR, 483, CO RESP 1/28/13
2013-6856	09/03/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/ OC/OCC/ ORA/OCI/ ORA/OCI/	Mona McCombs McCombs, Mona	PROTOCOL FOR TRANSPORTING ADULTERATED FOOD
2013-6857	09/03/2013 10/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Alan Katz BLOOMBERG NEWS	LIST OF DRUGS VOLUNTARILY WITHDRAWN BY SPONSOR, LIST OF DRUGS WITHDRAWN FOR SAFETY REASONS
2013-6858	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Christie Frayser Christie Frayser	ORTHO DIAGNOSTIC SYSTEMS, INC, RARITAN, NJ - LOT NUMBER RHL 265B, RHL 265K, RHL232A - MEDWATCH ALERTS, PROCESSING, POWDER SUBSTANCE ETC
2013-6859	09/03/2013 10/17/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dennis W. Raisch UNIVERSITY OF NEW MEXICO	RITUXIMAB - AERS

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6860	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Gina Pera Gina Pera	ANDA 202608 - BIOEQUIVALENCE STUDIES
2013-6861	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anita Fauchier Cempra Pharmaceuticals (Anita Fauchier)	WOCKHARDT, INDIA - RESPONSE TO 483
2013-6862	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Brenda Sweet TUCKER ELLIS LLP	JOHNSON & JOHNSON, HORSHAM, PA - EIR, 483 4/14/11, 10/2/09, ETC
2013-6863	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joyce Daubert Joyce Daubert	DICLEGIS - EFFICACY STUDIES
2013-6864	09/03/2013 10/17/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	Jonathan Rudner Ampro Industries, Inc.	KEYSTONE LABORATORIES, INC - WARNING LETTERS 01/01/2009 - 12/31/2011
2013-6865	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma, Inc.	NDA 011552
2013-6866	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 019478
2013-6867	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020198
2013-6868	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 018482

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-6869	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 019684
2013-6870	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 018333
2013-6871	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	RECS RE FOUR TOBACCO PRODUCTS DETERMINED NSE
2013-6872	09/03/2013 10/17/2013	FDA/OC/OES/DDM/	Joyce Daubert Joyce Daubert	BENDECTIN - ADVISORY COMMITTEE
2013-6873	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Vanessa Perez EXPONENT, INC.	CARBINOXAMINE CONTAINING DRUGS - DEATH REPORTS
2013-6874	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kara Plauger UPMC St. Margaret Hospital	FLUOROQUINOLONES - AERS
2013-6875	09/03/2013 10/17/2013	FDA/OF/CFSAN/OCDEOS/	Rachel Johnson FOI Services, Inc.	FCN 939
2013-6876	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	WELCH, HOLME, AND CLARK COMPANY, NEWARK, NJ - EIR, 483, RECALL 08/29/2011 - 08/29/2013
2013-6877	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michael Manapol Law Offices of Brian D. Witzer, Inc.	ANDA 065156
2013-6878	09/03/2013 10/17/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	John Walsh James Alexander Corporation	TOKYO CHEMICAL INDUSTRY COMPANY, LTD, PORTLAND, OR - EIR, 483 RECALLS 08/29/2010 - 08/29/2013
2013-6879	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway Lachman Consultants	ANDA 91052

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6880	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Julie Schoell Stryker IMT	K111970
2013-6881	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Oliver Clemens Materialise NV	K130126, K131129
2013-6882	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Christine Gassner GASSNER, VIRGINIA	MYSOLINE/PRIMIDONE - AERS 01/01/2011 - 09/01/2013
2013-6883	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Korey L Tichenor Smiles and Laughs Co.	STATISTICS COLLECTED BY FDA RE MQSA
2013-6884	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 019183
2013-6885	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOSEPH WALKER Walker, Joseph	TECFIDERA - ISR
2013-6886	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randy Veliky LEXINGTON CLINIC	K121920
2013-6887	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Randy Veliky Lexington Intl LLC	K113097
2013-6888	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randy Veliky Lexington Intl LLC	K122950
2013-6889	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	FOI DAILY LOG 8/1/13-31/2013
2013-6890	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	William H. Delp Delp, William H	MEDICAL DEVICES CLEARED TO BE MARKETING UNDER 868.5470
2013-6891	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr Stephen Garner Mathys & Squire LLP	SUGEN, INC - IND SU6668

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-6892	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	CLOSED FOIA REQUESTS ON CD 8/1-31/2013
2013-6893	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Faryal Hasan Hyman, Phelps & McNamara, P.C.	OFFICE OF GENERIC DRUGS STATISTICAL REPORT FOR JULY AND AUGUST 2013
2013-6894	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020142
2013-6895	09/03/2013 10/17/2013	FDA/OC/OES/DDM/	Ben Traywick Traywick Law Offices	JOINT MEETING OF THE ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE - TRANSCRIPT
2013-6896	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	TOBACCO SUBSTANTIAL EQUIVALENCE ORDERS
2013-6897	09/03/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K130793
2013-6898	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/ OC/OEXA/OPA/	Rachel Johnson FOI Services, Inc.	RECS RE CTP PRESS RELEASE
2013-6899	09/03/2013 10/17/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	Rachel Johnson FOI Services, Inc.	F&F FOODS, CHICAGO, IL - EIR
2013-6900	09/03/2013 10/17/2013	ORA/ ORA/ FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	David M Longseth Longseth, David M	SAMPLE RESULTS
2013-6901	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NANJING KING-FRIEND BIOCHEMICAL, CHINA - EIR, 483, ETC
2013-6902	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tina Lee Tris Pharma, Inc.	NDA 204242

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2013-6903	09/03/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/	James H. Botkin BOTKINCHEMIE	FAP Octadecanoic acid 2-2-hydroxyethyl) octadecylaminoethyl ester (CAS Reg. No. 52497-24-2), (octadecylimino) diethylene distearate (CAS Reg. No. 94945-28-5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213-78-2)
2013-6904	09/03/2013 10/17/2013	FDA/OC/OES/DDM/	Myra Wooley MASSACHUSETTS COLLEGE OF PHARMACY	1997 report by CDER titled "Retrospective review of ecotoxicity data submitted in environmental assessments for public display." (Docket No. 96N-0057)
2013-6905	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DOXYCYCLINE INJ ANDA 50-442 - APRVL LTR, LBLG, MEDICAL RVW, ETC
2013-6906	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DOXORUBINCIN LIPOSOME ANDA 50-718 - APRVL LTR, LBLG, MEDICAL RVW, ETC
2013-6907	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	VISTARIL (HYDROXYUZINE PALMOATE) NDA 11-459 - APRVL LTR, LBLG, MEDICAL RVW, ETC
2013-6908	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	DOXYCYCLINE INJ ANDA 62-475 - APRVL LTR, LBLG, MEDICAL RVWS, ETC
2013-6909	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	DR REDDY'S LABS LTD - ATORVASTATIN CALCIUM ORAL ANDA 091-650 - SBA
2013-6910	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	DR REDDY'S LABS LTD - ATORVASTATIN CALCIUM ANDA 203-257 SBA
2013-6911	09/03/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	YAW DAKO	GREGORY PACKAGING, NEWARK, NJ - EIR MOST RECENT

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	10/17/2013		COUNTRY PURE FOODS	
2013-6912	09/03/2013 10/17/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	YAW DAKO COUNTRY PURE FOODS	CITRUS SYSTEMS INC, HOPKINS, MN - EIR MOST RECENT
2013-6913	09/03/2013 10/17/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	YAW DAKO COUNTRY PURE FOODS	M&B JUICE, TAMPA, FL - EIR MOST RECENT
2013-6914	09/03/2013 10/17/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	YAW DAKO COUNTRY PURE FOODS	KING JUICE CO, MILWAUKEE, WI - EIR MOST RECENT
2013-6915	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	DAVID E OUTWATER OUTWATER & PINCKES LLP	ALCOA CIRCLE, CORONA, CA - POLYETHYLENE, PET BOTTLES & CONTAINERS SALES, LAB RPTS, WARNING LTRS, ETC 1/1/06 TO P RESENT
2013-6916	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SHEPPARD TARO PHARMACEUTICALS USA INC	AQUA PHARMS - CORDRAN LOTION TOPICAL NDA 13-790 SBA
2013-6917	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	RACHEL JOHNSON FOI Services, Inc.	OLMESARTAN - ISRS 6585297, 7454426, 7457740, ETC
2013-6918	09/03/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OC/OES/DFOI/	DANA HAYDEN Siegfried USA, LLC	PROPARACAINE HCL DMF 26989 - LIST OF CURRENT CUSTOMERS
2013-6919	09/03/2013 10/17/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	Doe J	GENERAL MILLS CEREAL LLC, GOLDEN VALLEY, MN - RAISIN NUT BRAN CEREAL CMLPNTS
2013-6920	09/03/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/	CARRIE L TEETER Keller and Heckman LLP	FCN 772
2013-6921	09/03/2013 10/17/2013	FDA/OMPT/CTP/OD/	MARILYNN WHITNEY COVINGTON & BURLING LLP	TOBACCO PRODS - EIGHT NOT SUBSTANTIALY EQUIVALENT (NSE) ORDERS, APPL, RVW, ETC
2013-6922	09/03/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/	HEALTHIER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	REGULATROY & OR ENFORCEMENT IN MEASURES PERTAINING TO USSE OF THE WORD FRESH IN FOOD LBLG - CORR RECS 9/08 TO PRESENT
2013-6923	09/03/2013 10/17/2013	FDA/OC/OES/DDM/ FDA/OF/CFSAN/OCD/EOS/	SYLVIA WU CENTER FOR FOOD SAFETY	DKT 2006P-0101/CP1

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2013-6924	09/03/2013 10/17/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHAEL PFEIL MERZ PHARMACEUTICALS GMBH	NOVARTIS VACCINES & DIAGNOSTICS INC USA 5/10/13; JANSSEN BIOLOGICS BV, NETHERLANDS; LONZA AG, SWITZERLAND 9/18/13 EIRS
2013-6925	09/03/2013 10/17/2013	CVM/OCD/	CYNDY BURINDA PHOENIX REGULATORY ASSOCIATES LTD	DIAMOND V - TRANSITION COW STUDIES CORR
2013-6926	09/03/2013 10/17/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	JENNIFER O'BRIAN AbbVie, Inc.	ABBVIE INC - IMPORTS, PREDICT SCORES 1/1/13-7/15/13
2013-6927	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-258
2013-6928	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-262
2013-6929	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8579
2013-6930	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8580
2013-6931	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8643
2013-6932	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8721

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2013-6933	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8730
2013-6934	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8782
2013-6935	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8567
2013-6936	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8988
2013-6937	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8992
2013-6938	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8993
2013-6939	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-8996
2013-6940	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2012-9094
2013-6941	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2420
2013-6942	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2421
2013-6943	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1523
2013-6944	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1542
2013-6945	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1596
2013-6946	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1951

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2013-6947	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1887
2013-6948	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1915
2013-6949	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2423
2013-6950	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1186
2013-6951	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1188
2013-6952	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1924
2013-6953	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1271
2013-6954	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2022
2013-6955	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2051
2013-6956	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1395
2013-6957	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2068
2013-6958	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1426
2013-6959	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2093
2013-6960	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2397
2013-6961	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1432
2013-6962	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1451
2013-6963	09/03/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-2110

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	10/17/2013		MERCK & CO., INC.	
2013-6964	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1479
2013-6965	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1921
2013-6966	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2305
2013-6967	09/03/2013 10/17/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2427
2013-6968	09/04/2013 10/02/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Paul Wagner Allianz	MTG MINUTES FROM 7/23/13 AND ANY PRE-MEETING AND POST-MEETING CORR BETWEEN FDA AND SAREPTA RE ETEPLIRSEN FOR TREATMENT OF DUCHENE'S MUSCULAR DYSTROPHY 01/01/2013 - 08/28/2013
2013-6969	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2221
2013-6970	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1700
2013-6971	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1701
2013-6972	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1702
2013-6973	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1805
2013-6974	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1835
2013-6975	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1836
2013-6976	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1884
2013-6977	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1704
2013-6978	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1719

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2013-6979	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1765
2013-6980	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1741
2013-6981	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1754
2013-6982	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1761
2013-6983	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1789
2013-6984	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1792
2013-6985	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) Phone - 267-305-7723 MERCK & CO., INC.	2013-742
2013-6986	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-756
2013-6987	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-789
2013-6988	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-794
2013-6989	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-792
2013-6990	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-802
2013-6991	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-799
2013-6992	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-800
2013-6993	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-803
2013-6994	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-811

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2013-6995	09/04/2013 10/02/2013	FDA/OGROP/OR/SE-FO/FLA-DO/FLA-CB/	DOUGLAS N BLUE II ZETETIC INC	SMITHS MEDICAL CATHETERS ENTRY #109-0875029-1 - RECS
2013-6996	09/04/2013 10/02/2013	OC/OL/	THOMAS H JONES 339 GROUP LLC	SEN MITCH MCCONNELL - FEDERAL FUNDING LEGISLATION, REGULATIONS, RECOMMENDATIONS, ETC CORR, RESP
2013-6997	09/04/2013 10/02/2013	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	SETH J MANFREDI GORDON & REES LLP	NEXT SEAFOOD INC, HAYWARD, CA - EIRS, TEST RESULTS, LTRS, ETC 2/22/08-12/31/08
2013-6998	09/04/2013 10/02/2013	FDA/OGROP/OR/PA-FO/SAN-DO/SAN-CB/	WILLIAM S NORTON MOTLEY RICE LLC	HOSPIRA INC, MORGAN HILL, CA - INSP 4/21-22/09 RECS
2013-6999	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-6529
2013-7000	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	ELENA HOWELL HOGAN LOVELLS LLP	2013-6250
2013-7001	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	DANYSH, KURT	MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES (MEDDRA)
2013-7002	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	DANYSH, KURT	ISRS 4638251-3, 4655315-9, 5074682-8, ETC
2013-7003	09/04/2013 10/02/2013	FDA/OGROP/OR/CE-FO/NWJ-DO/NWJ-CB/	TAMIKA L BELL BIOSCREEN TESTING SERVICES INC	BEAUTY-FILL, PISCATAWAY, NJ - EIRS, 483S, WARNING LTRS LAST 5 YRS
2013-7004	09/04/2013 10/02/2013	ORA/ORM/ ORA/ORM/	ROBERT KING FDA NEWS	PHARMACEUTICAL, BIOLOGICS, MEDICAL DVC MFG, CLNCL TRIAL FACILITIES IN AND OUTSIDE THE US - 483S 8/1-31/13
2013-7005	09/04/2013 10/02/2013	FDA/OF/CFSAN/OCD/EOS/	WILLIAM A OLSON PHD Center for Regulatory Services, Inc.	LYONDELL BASELL INDUSTRIES - ETHYLENE/PROPYLENE COPOLYMERS FCN 1051
2013-7006	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-809
2013-7007	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-812
2013-7008	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-833
2013-7009	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-876
2013-7010	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-974

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2013-7011	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1381
2013-7012	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1201
2013-7013	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1029
2013-7014	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-1061
2013-7015	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2212
2013-7016	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4627
2013-7017	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4636
2013-7018	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4862
2013-7019	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4864
2013-7020	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5178
2013-7021	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2929
2013-7022	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2947
2013-7023	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2963
2013-7024	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3050
2013-7025	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3296
2013-7026	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4349
2013-7027	09/04/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-2568

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	10/02/2013		MERCK & CO., INC.	
2013-7028	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2515
2013-7029	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2498
2013-7030	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2485
2013-7031	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2484
2013-7032	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4342
2013-7033	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2483
2013-7034	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4068
2013-7035	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4065
2013-7036	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4202
2013-7037	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3340
2013-7038	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2753
2013-7039	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-2602
2013-7040	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-3483
2013-7041	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-4586
2013-7042	09/04/2013 10/02/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	NATUREX - EIR, 483, RECALL 07/01/2011 - 09/03/2013
2013-7043	09/04/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	Richard O. Wood	ORGAN RECOVERY SYSTEMS, INC, ITASCA, IL - EIR, 483, 482 ETC 1/1/11 TO PRESENT

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	10/02/2013		the Wood Burditt group	
2013-7044	09/05/2013 10/03/2013	FDA/OC/OES/DDM/	COVINGTON & BURLING LLP	DKT FDA-1996-N-0050
2013-7045	09/05/2013 10/03/2013	FDA/OC/OES/DDM/	LAUREN FARRUGGIA Hyman, Phelps & McNamara, P.C.	DKT FDA-2013-P-0283
2013-7046	09/05/2013 10/03/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	TERRY SHAIN MEDICAL WASTE SERVICES	FDA MANDATED DESTRUCTION ACTIVITY LOS ANGELES, CA 1/12 TO 3/31/13
2013-7047	09/05/2013 10/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	ANDREA N. WALLEN DELPHINUS MEDICAL TECHNOLOGIES INC	IVU IMAGING CORP - SOFIA ATUS IMAGING DVC K080555
2013-7048	09/05/2013 10/03/2013	ORA/OCI/ ORA/OCI/	FRANK C. DAVIS MELODY CHRISTIAN ACADEMY	INDIVIDUAL RECS
2013-7049	09/05/2013 10/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	HEALY, HILARY	XOLAIR - AER
2013-7050	09/05/2013 10/03/2013	FDA/OF/CFSAN/OCD/EOS/	ERIC F. GREENBERG ERIC F GREENBERG PC	FCN 815
2013-7051	09/05/2013 10/03/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	NADIA A. PATEL BONNER KIERNAN TREBACH ET AL	NEW ENGLAND COMPOUNDING CTR, FRAMINGHAM, MA - METHYLPREDNISOLONE ACETATE INVESTIGATION, INSP, RECS
2013-7052	09/05/2013 10/03/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SUSAN E. SATKOWSKI LAVIN O'NEIL RICCI CEDRONE & DISIPIO	AVANTIX LABORATORIES; TDM PHARMACEUTICAL RESEARCH LLC - 482, 483, EIR, BIOEQUIV
2013-7053	09/05/2013 10/03/2013	ORA/ ORA/	BENJAMIN L. ENGLAND, Esq. BENJAMIN L ENGLAND &	FDA REGULATED ARTICLES 1/08 TO PRESENT

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		FDA/OGROP/ORO/ORO/DIOP/	ASSOCIATES LLC	
2013-7054	09/05/2013 10/03/2013	FDA/OMPT/CDRH/OCER/DFOI/	THOMAS TRIMNAL STERLING MEDICAL LLC..	HYSTEROSALPINGOGRAPHY & SONOHSTYEROGRAPHY CATHETER SET K092969
2013-7055	09/06/2013 10/04/2013	FDA/OC/OES/DDM/	JOANNA MCCALL NATIONAL CORPORATE RESEARCH	DKT FDA-1996-N-0050
2013-7056	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K051671
2013-7057	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman Medos Medizintechnik AG	K090449
2013-7058	09/06/2013 10/04/2013	FDA/OGROP/ORO/SE-FO/FLA-DO/FLA-CB/	Richard O. Wood the Wood Burditt group	UNIVERSITY OF FLORIDA, CERHB, FLORIDA BIOLOGIX, ALACHUA, FL - - 482, 483 EIR ETC
2013-7059	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jeanmarie Sales MEDTRONIC	K123633
2013-7060	09/06/2013 10/04/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	Jason A Dean Hulsey Oliver & Mahar, LLP	AMERICAN CUSTOM BLENDERS, LLC, JEFFERSON, GA - 01/01/2011 - 09/03/2013
2013-7061	09/06/2013 10/04/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA DISCLOSURE LOG (08/26/2013 - 08/30/2013)
2013-7062	09/06/2013 10/04/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OC/OES/DFOI/	Mark Skertic Mark Skertic	RANBAXY PHARMACEUTICALS - PREVIOUSLY RELEASED RECORDS 04/01/2004 - 06/01/2013
2013-7063	09/06/2013 10/04/2013	FDA/OGROP/ORO/NE-FO/NYK-DO/NYK-DCB/	John Walsh James Alexander Corporation	SCHOTT GLASS, ELMSFORD, NY - EIR, 483, RECALL (08/01/2011 - 09/03/2013)
2013-7064	09/06/2013 10/04/2013	FDA/OGROP/ORO/SE-FO/ATL-DO/ATL-CB/	John Walsh James Alexander Corporation	POREX TECHNOLOGIES, FAIRBURN, GA - 483, EIR, RECALL 06/01/2011 - 09/03/2013;
2013-7065	09/06/2013 10/04/2013	FDA/OGROP/ORO/CE-FO/MIN-DO/MIN-CB/	John Walsh James Alexander Corporation	TEEL PLASTICS, INC, BARABOO, WI - 483, EIR, RECALL 08/01/2011 - 09/03/2013
2013-7066	09/06/2013 10/04/2013	FDA/OGROP/ORO/CE-FO/BLT-DO/BLT-CB/	John Walsh James Alexander Corporation	KLOCKNER PENTAPLAST OF AMERICA, INC, GORDONSVILLE, VA - 483, EIR, RECALL 08/01/2011 - 09/03/2013
2013-7067	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tina Wu APTIV SOLUTIONS	K120218 K113655 K113222 ETC

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2013-7068	09/06/2013 10/04/2013	FDA/OC/OES/DFOI/ FDA/OF/CFSAN/OCD/EOS/	Daria Church Clariant Corporation	FCN 809
2013-7069	09/06/2013 10/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Tina Lee Tris Pharma Inc.	NDA 020450
2013-7070	09/06/2013 10/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jonathan J. Darrow BRIGHAM AND WOMEN'S HOSPITAL	RECS THAT SUMMARIZE NOVEL NEW DRUGS APPROVED IN EACH CALENDAR 01/01/1979 - 12/31/2010
2013-7071	09/06/2013 10/04/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OC/OES/DDM/	Beth Briczinski NATIONAL MILK PRODUCERS FEDERATION	FDA-2013-N-0888 - PETITION
2013-7072	09/06/2013 10/04/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ ORA/ ORA/	Mark Wolfe Tom Rhodes Law Firm, P.C.	SPECIALTY COMPOUNDING RECALL OF CALCIUM GLUCONATE
2013-7073	09/06/2013 10/04/2013	FDA/OMPT/OSMP/OOPD/	Orphan Designation Request for Qutenza LCC Consulting, LLC	QUTENZA - ORPHAN PRODUCT DESIGNATION
2013-7074	09/06/2013 10/04/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Mary Clare Jalonick THE ASSOCIATED PRESS	TAYLOR FARMS DE MEXICO - 483, INVESTIGATION RECS 09/01/2003 - 09/03/2013
2013-7075	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	RON JEFFREY CAS MEDICAL SYSTEMS INC	NONIN MEDICAL INC - K102715

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2013-7076	09/06/2013 10/04/2013	FDA/OMPT/CDRH/OCER/DFOI/	XIN MENG III SOLUTION LABORARY	SYNAPSE 3D LUNG & ABDOMEN ANAYLIS - K130542; MIPLATFORM MEDICAL IMAGING SUITE - K131424
2013-7077	09/06/2013 10/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	ATORVASTATIN CALCIUM TABS - ANDA 91-650, 203-257 BIOEQV RVWS, MODULE 3.2P.1 COMPOSITION SECTION
2013-7078	09/06/2013 10/04/2013	FDA/OF/CFSAN/OCD/EOS/	HEALTHER M HAUGHEY ROCKY MOUNTAIN POISON AND DRUG CENTER	RED BULL, MONSTER, ROCK STAR, ETC - CAERS 2010 TO PRESENT
2013-7079	09/06/2013 10/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAUDLE #20711-058, BRANDON LEE	TRUVADA - PI
2013-7080	09/06/2013 10/04/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Barbara Kowinsky KOWINSKY, BARBARA	BASF Grenzach GmbH - EIR JULY 2011
2013-7081	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	ATLANTIC SCALE COMPANY, NUTLEY, NJ - EIR, 483, RECALL (04/01/2011 - 09/03/2013) ;
2013-7082	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	BRANDT BOX & PAPAER CO, COLUMBIA, NJ - EIR, 483, RECALL 08/01/2011 - 09/03/2013
2013-7083	09/06/2013 10/04/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	John Walsh James Alexander Corporation	ACCU-GLASS LLC, ST LOUIS, MO - EIR, 483, RECALL 08/01/2011 - 09/03/2013
2013-7084	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	FRUTAROM USA, INC, NORTH BERGEN, NJ - EIR, 483, RECALL 06/01/2011 - 09/03/2013
2013-7085	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	GERRESHEIMER GLASS INC, VINELAND, NJ - EIR, 483, RECALL 07/01/2011 - 09/03/2013
2013-7086	09/06/2013 10/04/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	John Walsh James Alexander Corporation	MID-YORK PRESS, INC, SHERBURNE, NY - EIR, 483, RECALL 07/01/2011 - 09/03/2013
2013-7087	09/06/2013 10/04/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	John Walsh James Alexander Corporation	STERIPRO LABS, ITASCA, IL - EIR, 483, RECALL 08/01/2011 - 09/03/2013
2013-7088	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 22047 S 11

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2013-7089	09/09/2013 10/07/2013	CVM/OCD/	Sandy O'Kelley Merial Limited	AGRI-MECTIN PLUS CLORSULON - FOIA SUMMARY
2013-7090	09/09/2013 10/07/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	John Walsh James Alexander Corporation	TECTUBES USA, VINELAND, NJ - EIR, 483, RECALL
2013-7091	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	510K REDACTED AND RELEASED IN AUGUST 2013 NOT SENT TO FOI SERVICES
2013-7092	09/09/2013 10/07/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	John Walsh James Alexander Corporation	STERIGENICS, WILLOWBROOK, IL - EIR, 483, RECALL
2013-7093	09/09/2013 10/07/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	Remel, Inc. Fresenius Kabi USA, LLC	REMEL, INC, LENEXA, KS - 483, RESPONSE 01/01/2010 - 09/03/2013
2013-7094	09/09/2013 10/07/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	John Walsh James Alexander Corporation	INHANCE TECHNOLOGIES, ALLENTOWN, PA - EIR, 483, RECALL 06/01/2011 - 09/03/2013
2013-7095	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	John Brown J Brown Enterprises	K052925, K991430
2013-7096	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Anna Azvolinsky Anna Azvolinsky	ANDA 077425
2013-7097	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Sun Choi ADVANCED STERILIZATION PRODUCTS	K111391, K111375, K111377
2013-7098	09/09/2013 10/07/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	Eric Young Kessler Topaz Meltzer Check LLP	ST JUDE MEDICAL - EIR 6/8/2009 TO 7/8/2009, ATTACHMENT 5
2013-7099	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Alan Katz BLOOMBERG NEWS	ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE MEETINGS RE MDR-TB - MINUTES 06/01/2009 - 11/29/2012
2013-7100	09/09/2013 10/07/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/ CVM/OCD/	Doe J	INDIVIDUAL RECS
2013-7101	09/09/2013 10/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jonathan Siegel Kingdon Capital Management	SANQUIN PLASMA PRODUCTS, AMSTERDAM, NETHERLANDS - 483, EIR 05/15/2013 - 09/04/2013

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2013-7102	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	4MEI IN SOFT DRINKS - FOIA REQUESTS
2013-7103	09/09/2013 10/07/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	4MEI IN SOFT DRINKS AND CARAMEL COLOR - CORR
2013-7104	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Alberto Soler Alberto Soler	42 FR 14308
2013-7105	09/09/2013 10/07/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	LALILAB4055 LALILAB, INC.	Entry # 523-1008810-0 ANALYTICAL WORKSHEETS
2013-7106	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Lon Schneider MD Lon Schneider MD	PERIPHERAL AND CNS DRUGS ADVISORY COMMITTEE MEETINGS - AGENDAS, ROSTERS, MINUTES ETC 01/01/1989 - 01/01/1999
2013-7107	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Vikas Narang GPC Medical Limited	K070761;
2013-7108	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Chiedozie Ayika Heywood Hospital	FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection - AERS REPORTING
2013-7109	09/09/2013 10/07/2013	ORA/ ORA/	Derrick Gingery THE PINK SHEET	FORM 483 FOR QUALITY AND STERILITY TESTING LABORATORIES RE COMPOUNDING PHARMACIES 01/01/2013 - 09/04/2013
2013-7110	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Jorge Flores P.A Alberto Soler	35 FR 18623 Dec. 12, 1970; 36 FR 12093 June 25, 1971; 37 FR 25705 Dec. 2, 1972 ETC
2013-7111	09/09/2013 10/07/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Peter T. Anderson, Esq. Ashcraft& Gerel	MEDTRONIC MINIMED PARADIGM INSULIN INFUSION SET - RECALL RECS
2013-7112	09/09/2013 10/07/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Peter Waldran BAYER HEALTHCARE	JUBILANT-HOLLISTERSTIER, SPOKANE, WA - EIR, 483, WARNING LETTER 09/01/2005 - 09/01/2013
2013-7113	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	JOSEPH WALKER Walker, Joseph	COMPLAINTS MADE TO DSI RE CLINICAL TRIAL RECRUITMENT OR CLINICAL TRIAL MARKETING
2013-7114	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Meghan Lewallen MELLINO ROBENALT LLC	SCOPOLAMINE - MEDWATCH FORMS; PADER; PSUR

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2013-7115	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter R. Breggin, MD Center for the Study of Empathic Therapy	METOCLOPRAMIDE - SRS SPONTANEOUS REPORTING SYSTEM SUMMARY DATA
2013-7116	09/09/2013 10/07/2013		Rachel Johnson FOI Services, Inc.	GRANDFATHERED TOBACCO PRODUCTS
2013-7117	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ CVM/OCD/	Amy Babcock Hudson Highlands Veterinary Medical Group	INDIVIDUAL RECS
2013-7118	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Lorraine Barde Lorraine Barde	ALPRAZOLAM - AERS, STUDIES
2013-7119	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lalit Ortho Care	DATA OF TECHNOLOGICAL CHARACTERISTICS AND BIOMECHANIAL TESTING/BENCH TESTING OF PREDICATE DEVICES
2013-7120	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Jessica Kelly South Carolina Attorney General's Office	YASMIN - AERS
2013-7121	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Jessica Kelly South Carolina Attorney General's Office	YAZ - AERS
2013-7122	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Hollie Lawrence Regions Hospital	LIDODERM PATCH - AERS
2013-7123	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jennifer Janisch CBS NEWS	ALL ADVERSE EVENTS REPORTED TO THE FDA BY DEPARTMENT OF DEFENSE EMPLOYEES, TO INCLUDE TRICARE EMPLOYEES, MILITARY DOCTORS, MILITARY PHARMACISTS, AND ANY OTHER DEPARTMENT OF DEFENSE EMPLOYEE FOR THE DRUG MEFLOQUINE

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2013-7124	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman Medos Medizintechnik AG	K090450
2013-7125	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Wendy Taylor TAYLOR, WENDY	K090850, K082575, K081979 ETC
2013-7126	09/09/2013 10/07/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	John Walsh James Alexander Corporation	NICOSIN EXTRUSION, BRAZIL, IN - EIR, 483, RECALL 09/05/2010 - 09/05/2013
2013-7127	09/09/2013 10/07/2013	FDA/OF/CFSAN/OCD/EOS/	Mitchell Cheeseman Steptoe & Johnson LLP	FAP 5A4459, 5A4460
2013-7128	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Gary J Syring Gary Syring	K112102, K120450
2013-7129	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K102469
2013-7130	09/09/2013 10/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Dolly Pena NA	ESSURE - CLINICAL STUDIES
2013-7131	09/09/2013 10/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Ingrid Hoos Horizon Pharma, Inc.	NDA 022304
2013-7132	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OF/CFSAN/OCD/EOS/	Eun Bang, Eun	K122389
2013-7133	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K130932
2013-7134	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	P850007/S005
2013-7135	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	P850007/S004
2013-7136	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Sun Sol Enterprises	K092240
2013-7137	09/09/2013 10/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 202515

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7138	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michele Sinoway LACHMAN CONSULTANT SERVICES, INC.	ANDA 090431
2013-7139	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	ALCON LABORATORIES, CORK, IRELAND - EIR 02/21/2011 - 02/24/2011
2013-7140	09/09/2013 10/07/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	TCheney TC Consulting	HENRY FRAZER, PHARMD, MONTGOMERY, AL - 483 09/24/2012 - 10/03/2102
2013-7141	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Leann Christman Medos Medizintechnik AG	HILITE 7000, 7000 LT 510K
2013-7142	09/09/2013 10/07/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/	Beverly Ann Sakuda THE QUEEN'S MEDICAL CENTER	OXYELITE PRO - AERS
2013-7143	09/09/2013 10/07/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Shin Kang WELLS FARGO	BIOMARIN - 483, REPSONSE, EIR 01/01/2013 - 09/05/2013
2013-7144	09/09/2013 10/07/2013	CVM/OCD/ FDA/OC/OES/	Lewis Bollard Humane Society of the United States	ZIMLAX - CORR, SUSPENSION, STUDIES ETC
2013-7145	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Sara Green MERRIMACK PHARMACEUTICALS INC	FDA STAFF MANUAL GUIDE 4850.7
2013-7146	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	SHENZHEN ANT HI-TECH INDUSTRIAL CO., LTD - APPROVAL RECS FOR HIGH PRESSURE SYRINGES
2013-7147	09/09/2013 10/07/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/	DEVA SUNDARARAJAN GLOBAL TRADE INTELLIGENCE INC	IMPORT RECS 7/1/13 TO PRESENT

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2013-7148	09/09/2013 10/07/2013	FDA/OF/CFSAN/OCD/EOS/	ANDREA STOUT HEEKIN & HEEKIN	MT HEALTHY HATCHERIES - SALMONELLA CONTAMINATION INVESTIGATION RECS 4/11
2013-7149	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	DANYSH, KURT	INDIVIDUAL RECS
2013-7150	09/09/2013 10/07/2013	CVM/OCD/ FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CTP/OD/ OC/OCC/	JANICE M HOGAN HOGAN LOVELLS LLP	LIST OF SPECIAL GOVERNMENT EMPLOYEES WHO COULD SERVE AS TEMPORARY VOTING MEMBERS FOR FDA A/C MTGS
2013-7151	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KAITLYN N DAY WARNER NORCROSS & JUDD LLP	XELLIA PHARMS - BACITRACIN CORR
2013-7152	09/09/2013 10/07/2013	FDA/OF/CFSAN/OCD/EOS/	DON M OBERT COWAN LIEBOWITZ & LATMAN PC	LIN'S WAHA USA INTERNATIONAL CORP - ENTRY #U79- 1682226-6 LAB RPTS, EIRS, 483S, ETC
2013-7153	09/09/2013 10/07/2013	FDA/OF/CFSAN/OCD/EOS/	DON M OBERT COWAN LIEBOWITZ & LATMAN PC	LIN'S ENTERPRISE (USA) INC - ENTRY #ES3-2070142-9 LAB RPTS, EIRS, 483S, ETC
2013-7154	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	MICHELE L BUENAFE MORGAN LEWIS & BOCKIUS LLP	LED INTELLECTUAL PROPERTIES LLC - LIGHTSTIM K120775, K101190
2013-7155	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CINIMERA, KRISTA	OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION INC - TOLVAPTAN COMPLETE RESP LTR 8/29/13
2013-7156	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	CHRISTOPHER VAN GUNDY ROLL LAW GROUP PC	DETROIT RECS - MINOR DELETIONS
2013-7157	09/09/2013	FDA/OC/OES/DFOI/	CHRISTOPHER VAN GUNDY	LOS ANGELES RECS - MINOR DELETIONS

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	10/07/2013		ROLL LAW GROUP PC	
2013-7158	09/09/2013 10/07/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/ FDA/OGROP/ORA/SW-FO/SWID/SWID-CB/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	MARROKO VALLEY LLC - ENTRY #BYX00637516, #BYX00633887 NOTICES FOR REQUEST OF INFORMATION (CF28), FDA NOTICE OF ACTION, CBP REDELIER NOTICES (CF4647), ETC
2013-7159	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K972768
2013-7160	09/09/2013 10/07/2013	FDA/OO/OFBA/OAGS/	Maria Herbert MCH Consulting Services	TOBACCO TRIBAL COMPLIANCE OUTREACH AND COMMUNICATIONS FDA-13-223-SOL-00071; THIRD PARTY AUDIT RECALL 12-223-SOL-00100
2013-7161	09/09/2013 10/07/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Robert King FDANEWS	BELCHER PHARMACEUTICALS, LARGO, FL - 483
2013-7162	09/09/2013 10/07/2013	ORA/ ORA/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Robyn M. Buckley York Williams, LLP	CONSUMER COMPLAINT 115081
2013-7163	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Ingrid Hoos Horizon Pharma, Inc.	NDA 200533
2013-7164	09/09/2013 10/07/2013	FDA/OO/OFBA/OAGS/	Michelle Seissler FEFA LLC	HHSF223201110113A
2013-7165	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marie Thibault LAZARD CAPITAL MARKETS	CARDIOMEMS' CHAMPION HF MONITORING SYSTEM - ADDITIONAL DATA SUBMISSION
2013-7166	09/09/2013 10/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Rachel Johnson FOI Services, Inc.	VACCINE LICENSE NUMBER 3
2013-7167	09/09/2013 10/07/2013	FDA/OC/OES/DDM/	Richard B. Smith, Ph.D. Richard B. Smith, Ph.D.	OPHTHALMIC DEVICES PANEL - TRANSCRIPTS 01/01/1995 - 12/31/1996
2013-7168	09/09/2013 10/07/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/	Kerry Thacker Kerry Thacker	IND 15376

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		ALFB/		
2013-7169	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dr Andrew Naylor Newcastle University	HDE H010005
2013-7170	09/09/2013 10/07/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 5B3894, 8B4071
2013-7171	09/09/2013 10/07/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	Ortav Yehudai Great Point Partners, LLC	OSIRIS THERAPEUTICS, COLUMBIA, MD - 483, WARNING LETTER, UNTITLED LETTER
2013-7172	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K030197
2013-7173	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Adrinee Azariance Huntington Memorial Hospital Inpatient Pharmacy	PHARMEDIUM SERVICES, LLC - INSPECTION RECS
2013-7174	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Lillie Thomas ORTHOFIX INC.	K011965
2013-7175	09/09/2013 10/07/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Amy Tseng TissueTech, Inc.	TISSUE REFERENCE GROUP RECOMMENDATION DOCUMENTS
2013-7176	09/09/2013 10/07/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Greg Allison Greg Allison	ANDA 091189
2013-7177	09/09/2013 10/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Megan Healey Megan Healey	NEW ENGLAND CORD BANK - INSPECTION RECS 01/01/2013 - 09/08/2013
2013-7178	09/09/2013 10/07/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	Megan Healey Megan Healey	VIACORD - INSPECTION RECS 01/01/2013 - 09/08/2013
2013-7179	09/09/2013 10/07/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	Megan Healey Megan Healey	CORD BLOOD REGISTRY - INSPECTION RECS 01/01/2013 - 09/08/2013
2013-7180	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Quick Philips Healthcare Inc (Cleveland)	K083421
2013-7181	09/09/2013 10/07/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 9/2/2013 TO 9/6/2013
2013-7182	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Susan Quick Philips Healthcare Inc (Cleveland)	K121434
2013-7183	09/09/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	Steve Unwin	JAMES C FREEMAN, MD - RESPONSE TO 483

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	10/07/2013		Steve Unwin	
2013-7184	09/09/2013 10/07/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joseph Dohm TEL-Atomic Inc	THE SCIENCE SOURCE - ANNUAL REPORTS FOR RADIATION EMITTING PRODUCTS 06/30/2012 - 09/07/2013
2013-7185	09/10/2013 10/08/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	ROBERT KING FDA NEWS	BIOGEN IDEC, RESEARCH TRIANGLE PARK, NC - 483S 8/1-31/13
2013-7186	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	ROBERT KING FDA NEWS	KAWKNAD MANUFACTURING INDUSTRIES INC, ALEXANDRIA, VA; BARR LABORATORIES INC (TEVA), FOREST, VA; TETRACORE INC, ROCKVILLE, MD, ETC - 483S 8/1-31/13
2013-7187	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	ROBERT KING FDA NEWS	RSB SPINE LLC, CLEVELAND, OH - 483S 8/1-31/13
2013-7188	09/10/2013 10/08/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	ROBERT KING FDA NEWS	ARJOHUNTLEIGH INC, SAN ANTONIO, TX; RETRACTABLE TECHNOLOGIES INC, LITTLE ELM, TX; OTOTRONIX LLC, SPRING, TX, ETC - 483S 8/1-31/13
2013-7189	09/10/2013 10/08/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	ROBERT KING FDA NEWS	CME AMERICA LLC, GOLDEN, CO; PROVIDENCE GLOBAL MEDICAL INC, SALT LAKE CITY, UT; CORGENIX INC, BROOMFIELD, CO, ETC - 483S 8/1-31/13
2013-7190	09/10/2013 10/08/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	ROBERT KING FDA NEWS	TANGENT MEDICAL TECHNOLOGIES, INC, ANN ARBOR, MI; KING SYSTEMS CORP, NOBLESVILLE, IN; KREMERS URBAN PHARMACEUTICALS INC, SEYMOUR, IN, ETC - 483S 8/1-31/13
2013-7191	09/10/2013 10/08/2013	FDA/OGROP/ORASE-FO/FLA-DO/FLA-CB/	ROBERT KING FDA NEWS	GAMBRO RENAL PRODUCTS INC, DAYTONA BEACH, FL; BIOMET 3I LLC, PALM BEACH GARDENS, FL; FIBER OPTIC CABLES INC, LARGO, FL, ETC - 483S 8/1-31/13
2013-7192	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	ROBERT KING FDA NEWS	MAYNE PHARMA INTERNATIONAL PTY LTD, SALISBURY SOUTH AUSTRALIA; LABORATORIOS JALOMA SA DE CV, GUADALAJARA, MEXICO; MERK SA DE CV, NAUCALPAN DE JUAREZ, MEXICO, ETC - 483S 8/1-31/13
2013-7193	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	ROBERT KING FDA NEWS	MP BIOMEDICALS ASIA PACIFIC PTD LTD, SINGAPORE; PHILIPS & NEUSOFT MEDICAL SYSTEMS CO LTD, SHENYANG, CHINA; CHEEN HOUNG ENTERPRISE CO LTD, TAIPEI, TAIWAN, ETC - 483S 8/1-31/13
2013-7194	09/10/2013 10/08/2013	FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	ROBERT KING FDA NEWS	HOSPIRA INC, MCPHERSON, KS; WEXFORD LABS INC, KIRKWOOD, MO; CERTIFIED SAFETY MFG INC, KANSAS CITY, MO - 483S 8/1-31/13
2013-7195	09/10/2013 10/08/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	ROBERT KING FDA NEWS	SHIRE HUMAN GENETIC THERAPIES INC, CAMBRIDGE, MA; PHARMAGEN LABORATORIES INC, STAMFORD, CT; IMAGE DIAGNOSTICS INC, FITCHBURG, MA, ETC - 483S 8/1-31/13
2013-7196	09/10/2013	FDA/OGROP/ORACE-FO/NWJ-	ROBERT KING	PHARMACY CREATIONS, RANDOLPH, NJ; NOVEL

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	10/08/2013	DO/NWJ-CB/	FDA NEWS	LABORATORIES INC, SOMERSET, NJ; PROSEC PROTECTION SYSTEMS INC, LAKEWOOD, NJ - 483S 8/1-31/13
2013-7197	09/10/2013 10/08/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	ROBERT KING FDA NEWS	KEYSTONE LABORASTORIES INC, MEMPHIS, TN; GENERAL HEARING INSTRUMENTS INC, HARAHAH, LA - 483S 8/1-31/13
2013-7198	09/10/2013 10/08/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	ROBERT KING FDA NEWS	ULTRALAB LABORATORIES INC, HIGHLAND, NY; ESTEE LAUDER IN (LEN RON MFG), MELVILLE, NY; ALTAIRE PHARMACEUTICALS INC, AQUEBOGUE, NY, ETC - 483S 8/1-31/13
2013-7199	09/10/2013 10/08/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	ROBERT KING FDA NEWS	LANNETT COMPANY INC, PHILADELPHIA, PA; SIGMA PHARM LABORATORIES LLC, BENSALEM, PA - 483S 8/1-31/13
2013-7200	09/10/2013 10/08/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	ROBERT KING FDA NEWS	AMPAC FINE CHEMICALS LLC, RANCHO CORDOVA, CA - 483S 8/1-31/13
2013-7201	09/10/2013 10/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	ROBERT KING FDA NEWS	GREENWAY RESEARCH LAB, BURNSVILLE, MN; FONTAROME CHEMICAL INC, ST FRANCIS, WI; FONTAROME CHEMICAL INC, ST FRANCIS, WI; CONTINENTAL MEDICAL LABS INC, WATERFORD, WI - 483S 8/1-31/13
2013-7202	09/10/2013 10/08/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ROBERT KING FDA NEWS	KIRKMAN GROUP INC, LAKE OSWEGO, OR - 483S 8/1-31/13
2013-7203	09/10/2013 10/08/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	ROBERT KING FDA NEWS	PFIZER PHARMACEUTICALS INC, BARCELONETA, PR - 483S 8/1-31/13
2013-7204	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/ORA/ORA/	ROBERT KING FDA NEWS	LAERDAL MEDICAL A/S, STAVANGER, NORWAY 8/1-31/13
2013-7205	09/10/2013 10/08/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ROBERT KING FDA NEWS	SANITOR CORP, HUNTINGTON BEACH, CA; ALLIANCE MEDICAL PRODUCTS INC, IRVINE, CA; CAPCO CUSTOM PACKAGING INC, SANTA FE SPRINGS, CA, ETC - 483S 8/1-31/13
2013-7206	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Parul Chansoria STRYKER ENDOSCOPY	K954465
2013-7207	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Hiroaki Wakamoto JNC CORPORATION	K131619
2013-7208	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chris Smith Symmetry Medical Manufacturing, Inc.	K113776

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2013-7209	09/10/2013 10/08/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/	Brett Norman POLITICO	Letters from state legislators to Commissioner Margaret Hamburg regarding potential regulation of menthol cigarettes
2013-7210	09/10/2013 10/08/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Marc Eisen Freelance writer & editor Marc Eisen	QUINCY BIOSCIENCE, MADISON, WI - WARNING LETTER RECS
2013-7211	09/10/2013 10/08/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Patty Dold Dold, Patty	LIST OF DIALYSIS CLINICS IN US USING FESENIUM DIALYSATE GRANYFLO AND/OR NATURALYTE 07/01/2003 - 12/30/2012
2013-7212	09/10/2013 10/08/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Joy Flynn flynn, joy	WEST PHARMACEUTICALS, JERSEY SHORE, PA - EIR 11/03/2011 - 09/09/2013
2013-7213	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	Request for 510k STRYKER ENDOSCOPY	K083707
2013-7214	09/10/2013 10/08/2013	FDA/OF/CFSAN/OCD/EOS/	Larry Feinberg KnipBio	FAP 7C0283
2013-7215	09/10/2013 10/08/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Donna Cowan VeroScience LLC	PATHEON PHARMACEUTICALS INC, CINCINNATI, OH - EIR 01/01/2011 - 09/09/2013
2013-7216	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Dheeresh Pathak Dheeresh Pathak	WOCKHARDT, INDIA - 483 07/01/2013 - 09/10/2013
2013-7217	09/10/2013 10/08/2013	FDA/OC/OES/DFOI/	HERBST, JACQUELINE	COMMISSIONED CORP INVESTIGATION CRITERIA
2013-7218	09/10/2013 10/08/2013	FDA/OC/OES/DFOI/	HERBST, JACQUELINE	INDIVIDUAL RECS
2013-7219	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	GERRIE OLOVER DAVA PHARMACEUTICALS INC	DOXEPIN ANDA 71-673; 71-674; 71-675; 71-676; 71-685; 71-686 APRVL 1/5/88
2013-7220	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	HOLLAND, CHRIS	MARQIBO KIT (VINCRISTINE SULFATE) NDA 02-497 APRVL 8/9/12 - RVW
2013-7221	09/10/2013 10/08/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	BLOXIVERZ (NEOSTIGMAINE METHYL SULPHATE) NDA 04-078 - APRVL, LBLG, MEDICAL RVW, PHARMACOLOGY RVW,

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		CHEMISTRY RVW
2013-7222	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MICHAEL R. COHEN INSTITUTE FOR SAFE MEDICATION PRACTICES	REDACTED MEDWATCH RPTS 8/13
2013-7223	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	JUDY ZHU HANGZHOU CONOD MEDICAL CO LTD	K030813
2013-7224	09/10/2013 10/08/2013	FDA/OMPT/CDRH/OCER/DFOI/	RACHEL ROBERTS INDAGO GROUP	SURGICAL MESH FOR POP/SUI REPAIR - MDR RPTS 2000 TO PRESENT
2013-7225	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	TAMI DALBERG INDENA USA INC	SICOR DE MEXICO SA DE CV, MEXICO - 483 7/13
2013-7226	09/10/2013 10/08/2013	FDA/OC/OES/DDM/	MARK B. GOLDSTEIN POMERANTZ HUFFORD ET AL	TRANSCRIPT OF MTG OF BLOOD ADVISORY COMMITTEE 12/2/93
2013-7227	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	PAMELA SCHANEEN SHIONOGI INC	OSPHERA (OSPHEMIFENE) PHARMACOLOGY RVW UNREDACTED 4/25/12
2013-7228	09/10/2013 10/08/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM J. DUBANEVICH PARKER & WAICHMAN ATTYS	MERCK & CO - GLUCAGON LIKE PEPTIDE THERAPIES INVESTIGATIONS
2013-7229	09/11/2013 10/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MARILYNN WHITNEY COVINGTON & BURLING LLP	ANDA 77-425 - AMENDMENT COVER LTRS 4/13/12, 8/1/12, 8/8/12, 8/15/12, 9/28/12, 6/11/13 & 7/30/13
2013-7230	09/11/2013 10/09/2013	FDA/OF/CFSAN/OCDE/EOS/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WALTER G CRUMP GUY KORNBLUM & ASSOCIATES	NEXT SEAFOOD - RPTS, CORR, INVESTIGATION RECS, ETC
2013-7231	09/11/2013 10/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER HSIEH DEERFIELD INSTITUTE	RESULTS OF THE MEDSUN SURVEY REGARDING THE DA VINCI SURGICAL SYS

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2013-7232	09/11/2013 10/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	ELIZABETH FELT WAKEMAN ZUKOWSKI ROGERS FLOOD & MCARDLE LAW OFCS	SURGICAL MESH - EMAIL NOTIFICATIONS OR MAILINGS SENT TO PHYSICIANS 1/08 AND 1/09
2013-7233	09/11/2013 10/09/2013	FDA/OF/CFSAN/OCD/EOS/	FRIEDMAN, ROBERT	LEAN CUISINE, NUTRISYSTEM, HEALTHY CHOICE, ETC - CAERS 1969 TO 2013
2013-7234	09/11/2013 10/09/2013	FDA/OMPT/CDRH/OCER/DFOI/	HUNTINGTON, DAVID G	EDAP TMS SA CORP - ABLATHERM HIFU DVC MTG RECS 6/3/13
2013-7235	09/11/2013 10/09/2013	ORA/ORM/ ORA/ORM/	SASHA L PERKINS THOMSON REUTERS	DRUG MFRS, LABLERS, REPACKERS, ETC - FOREIGN AND DOMESTIC INSPS 3/1/13 TO PRESENT
2013-7236	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CURTIS HORN MD, SAN ANTONIO, TX - EIR, 483, CO RESP 2/13/12
2013-7237	09/11/2013 10/09/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	GENESIS PHARMACEUTICALS INC, HENDERSON, NV - EIR, 483, CO RESP 9/13/12
2013-7238	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAVID J PORTMAN MD, COLUMBUS, OH - EIR, 483, CO RESP 10/26/12
2013-7239	09/11/2013 10/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	CENEXI LABORATORIES THISSEN SA, BRAINE L'ALLEUD, BELGIUM - EIR, 483, CO RESP 7/17/12
2013-7240	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	WALTER E CHALKLEY THOMSON REUTERS	BIORELIANCE CORP, ROCKVILLE, MD - EIR, 483, CO RESP 7/3/12
2013-7241	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	AUXILIUM PHARMACEUTICALS INC, HORSHAM, PA - EIR, 483, CO RESP 7/6/12
2013-7242	09/11/2013 10/09/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	WILLIAM M KUFES MD, SARATOGA SPRINGS, NY - EIR, 483, CO RESP 2/9/12
2013-7243	09/11/2013 10/09/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	VERTEX PHARMACEUTICALS INC, CAMBRIDGE, MA - EIR, 483, CO RESP 1/13/12
2013-7244	09/11/2013 10/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	UNICHEM LABORATORIES LTD, GOA, INDIA - EIR, 483, CO RESP 4/6/12
2013-7245	09/11/2013 10/09/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	TAKEDA PHARMACEUTICAL CO LTD, OSAKA, JAPAN - EIR, 483, CO RESP 8/2/12

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7246	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	WALTER E CHALKLEY THOMSON REUTERS	STERIS ISOMEDIX SERVICES INC, SANDY, UT - EIR, 483, CO RESP 3/21/12
2013-7247	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	SANOFI-AVENTIS US LLC, ST LOUIS, MO - EIR, 483, CO RESP 3/14/12
2013-7248	09/11/2013 10/09/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	ROBIN KROLL MD, SEATTLE, WA - EIR, 483, CO RESP 12/20/12
2013-7249	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	PFIZER PHARMACEUTICALS LLC, VEGA BAJA, PR - EIR, 483, CO RESP 8/10/12
2013-7250	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	OAKWOOD LABORATORIES LLC, SOLON, OH - EIR, 483, CO RESP 9/20/12
2013-7251	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	NESHER PHARMACEUTICALS (USA) LLC, BRIDGETON, MO - EIR, 483S, CO RESP 12/6/12
2013-7252	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/SJN-DO/SJN-CB/	WALTER E CHALKLEY THOMSON REUTERS	ABBVIE BIOTECHNOLOGY LTD, BARCELONETA, PR - EIR, 483, CO RESP 7/2/12
2013-7253	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAKOTA LABORATORIES LLC, MITCHELL, SD - EIR, 483, CO RESP 4/5/12
2013-7254	09/11/2013 10/09/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAKOTA LABORATORIES LLC, MITCHELL, SD - EIR, 483, CO RESP 8/31/11
2013-7255	09/11/2013 10/09/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/ FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	DAKOTA LABORATORIES LLC, ST LOUIS, MO - EIR, 483, CO RESP 6/22-24/10
2013-7256	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	STEWART PHARMACEUTICALS INC (STEWART COMPOUNDING PHARMACY), FAYETTEVILLE, NC - EIR, 483, CO RESP 3/18-25/13
2013-7257	09/11/2013 10/09/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	WALTER E CHALKLEY THOMSON REUTERS	HENRY A FRAZER PHARM D, MONTGOMERY, AL - EIR, 483, CO RESP 9/24/12-10/3/12
2013-7258	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Peter Waldran BAYER HEALTHCARE	NELSON LABS, SALT LAKE CITY, UT - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7259	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Peter Waldran BAYER HEALTHCARE	AAI PHARMA, WILMINGTON, NC - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7260	09/12/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Peter Waldran	IRVINE PHARMACEUTICAL, IRVINE, CA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013

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	10/10/2013		Berkeley Healthcare	
2013-7261	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Peter Waldran BAYER HEALTHCARE	EUROFINS LANCASTER LABORATORIES, LANCASTER, PA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7262	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Peter Waldran BAYER HEALTHCARE	COVIDIEN, AUGUSTA, GA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7263	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	Peter Waldran BAYER HEALTHCARE	COVIDIENT, DELAND, FLA - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7264	09/12/2013 10/10/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Peter Waldran BAYER HEALTHCARE	TERUMO MEDICAL CORPORATION, PHOENIX, AZ -EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7265	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Peter Waldran BAYER HEALTHCARE	BD MEDICAL SYSTEMS, FRANKLIN LAKES, NJ - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7266	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	Peter Waldran BAYER HEALTHCARE	BD MEDICAL, SANDY, UT - EIR, 483, RESPONSE 09/08/2008 - 09/08/2013
2013-7267	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	PENTA MANUFACTURING COMPANY, LIVINGSTON, NJ - EIR, 483, RESPONSE 09/09/2010 - 09/09/2013
2013-7268	09/12/2013 10/10/2013	CVM/OCD/	David L Fisher Freeport-McMoRan Sales Company	INADA 010-046-Hoo6 - MANUFACTURING CHEMISTRY SECTION
2013-7269	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	William R. Myers Myers, William R	ESSURE - POST APPROVAL STUDIES
2013-7270	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Robert Mahler Ansell Healthcare Products LLC	K100635
2013-7271	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K120012
2013-7272	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K071079
2013-7273	09/12/2013 10/10/2013	FDA/OF/CFSAN/OCD/EOS/	Mitchell A. Cheeseman Cheeseman, Mitch	FCN 62
2013-7274	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL MARTOS Martos, Arden	K954707
2013-7275	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL MARTOS Martos, Arden	K050907
2013-7276	09/12/2013	FDA/OMPT/CDRH/OCER/DFOI/	DANIEL MARTOS	K933433

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	10/10/2013		DANIEL MARTOS	
2013-7277	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Salyton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589 S019
2013-7278	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589 S17
2013-7279	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 201292 S 001
2013-7280	09/12/2013 10/10/2013	FDA/OC/OES/DDM/	Katherine Giannamore The Law Office of Katherine Giannamore, PA	DKT. 80N-0146
2013-7281	09/12/2013 10/10/2013	FDA/OF/CFSAN/OCDEOS/	Mitchell A. Cheeseman Cheeseman, Mitch	FCN 185
2013-7282	09/12/2013 10/10/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Michelle Daniels Daniels, Michelle	LISTING OF DESI PRODUCTS CURRENTLY ON THE MARKET
2013-7283	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheena M. Posey Norris The National Academies (Institute of Medicine)	NDA 022244 - ACTION LETTER
2013-7284	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	BLA 103000 S5050
2013-7285	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Zwernemann Infinite Biomedical Technologies,	K032833

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			LLC	
2013-7286	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kyan Mulligan none	DR REDDY QUENTIAPINE FUMARATE - AERS
2013-7287	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	John Franolic VersaPharm Inc.	ANDA 078854
2013-7288	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K112094
2013-7289	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K990278
2013-7290	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K032054
2013-7291	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K060808
2013-7292	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K924348
2013-7293	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	MANISH AHUJA BIO TEX INC	K971247
2013-7294	09/12/2013 10/10/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	JABONES PARDO SA MADRID, SPAIN - EIRS, 483S, CO RESP 03/11-14/113
2013-7295	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	IBI-ISTITUTO BIOCHIMICO ITALIANO GIOVANNI LORENZINI SPA, APRILLA, ITALY - EIRS, 483S, CO RESP 10/05/12
2013-7296	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	CATALENT PHARMA SOLUTIONS LLC, SOMERSET, NJ - EIRS, 483S, CO RESP 12/19/12
2013-7297	09/12/2013	FDA/OGROP/ORA/PA-FO/SAN-	WALTER E CHALKLEY	AMGEN INC, THOUSAND OAKS, CA - EIRS, 483S, CO RESP

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	10/10/2013	DO/SAN-CB/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	THOMSON REUTERS	12/12/12
2013-7298	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CHI- DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	SA ANALYTICAL LLC, MUNDELEIN, IL - EIRS, 483S, CO RESP 01/16/13
2013-7299	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	LOWELL ROGER, EVANSVILLE, IN - EIRS, 483S, CO RESP 01/03/13
2013-7300	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	INTERSTATE BLOOD BANK INC, PHILADELPHIA, PA - EIRS, 483S, CO RESP 03/12/13
2013-7301	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	HOXWORTH BLOOD CENTER, FORT MITCHELL, KY - EIRS, 483S, CO RESP 01/07/13
2013-7302	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/DAL- DO/DAL-CB/	WALTER E CHALKLEY THOMSON REUTERS	CARTER BLOOD CARE - CEDAR HILL DONATION CENTER, CEDAR HILL, TX - EIRS, 483S, CO RESP 02/02/13
2013-7303	09/12/2013 10/10/2013	FDA/OGROP/ORA/NE-FO/NYK- DO/NYK-DCB/	WALTER E CHALKLEY THOMSON REUTERS	GRIFOLS THERAPEUTICS INC, MELVILLE, NY - EIRS, 483S, CO RESP 09/02/12
2013-7304	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	AULTMAN HOSPITAL, CANTON, OH - EIRS, 483S, CO RESP 02/08/13
2013-7305	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	RARITAN PHARMACEUTICALS INC, EAST BRUNSWICK, NJ - EIRS, 483S, CO RESP 09/19/12
2013-7306	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/DET- DO/DET-CB/	WALTER E CHALKLEY THOMSON REUTERS	MONOSOL RX LLC, PORTAGE, IN - EIRS, 483S, CO RESP 09/13/12
2013-7307	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	LTS LOHMANN THERAPY SYSTEMS CORP, WEST CALDWELL, NJ - EIRS, 483S, CO RESP 09/11/12
2013-7308	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	WALTER E CHALKLEY THOMSON REUTERS	BETHESDA MEMORIAL HOSPITAL IRB, BOYNTON BEACH, FL - EIRS, 483S, CO RESP 09/07/12
2013-7309	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	WALTER E CHALKLEY THOMSON REUTERS	YONSUNG FINE CHEMICALS CO LTD, GYEONGGI-DO, SOUTH KOREA - EIRS, 483S, CO RESP 10/25/12
2013-7310	09/12/2013 10/10/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	WALTER E CHALKLEY THOMSON REUTERS	APTUIT (SCIENTIFIC OPERATIONS) LLC, HARRISONVILLE, MO - EIRS, 483S, CO RESP 11/14/12
2013-7311	09/12/2013 10/10/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	WALTER E CHALKLEY THOMSON REUTERS	BOSTON ANALYTICAL LINC, SALEM, NH - EIRS, 483S, CO RESP 11/09/12

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2013-7312	09/12/2013 10/10/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/ FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	WALTER E CHALKLEY THOMSON REUTERS	MARK B FARIES MD, SANTA MONICA, CA - EIRS, 483S, CO RESP 11/30/12
2013-7313	09/12/2013 10/10/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	WALTER E CHALKLEY THOMSON REUTERS	SIGHTLIFE, SEATTLE, WA - EIRS, 483S, CO RESP 12/17/12
2013-7314	09/12/2013 10/10/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	WALTER E CHALKLEY THOMSON REUTERS	ATLANTA BLOOD SERVICES, MARIETTA, GA - EIRS, 483S, CO RESP 03/20/13
2013-7315	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	WALTER E CHALKLEY THOMSON REUTERS	MERICON INDUSTRIES INC, PEORIA, IL - EIRS, 483S, CO RESP 04/27/12
2013-7316	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	WALTER E CHALKLEY THOMSON REUTERS	LAMBDA RESEARCH INC, CINCINNATI, OH - EIRS, 483S, CO RESP 04/27/12
2013-7317	09/12/2013 10/10/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	WALTER E CHALKLEY THOMSON REUTERS	JACOBUS PHARMACEUTICAL COMPANY, INC, PLAINSBORO, NJ - EIRS, 483S, CO RESP 04/16/12
2013-7318	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	RICHARD KAPLAN GENERAL SLEEP CORP	ADVANCED BRAIN MONITORING INC, CARLSBAD, CA - K120450
2013-7319	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	DEBORAH LAVOIE GRAYSESKI M SQUARED ASSOCIATES INC	IMPLEMENTATION OF SECTION 216 & THE REQUIREMENTS TO FULFILL SIMILARITY OF A PROD IN TO THE APRVD PRODIN CONTEXT OF EVOKING SECTION 216
2013-7320	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	CHARLES CELESTE EAS CONSULTING GROUP LLC	OXCARBAZEPINE ORAL SUSPENSION 300 MG/5ML ANDA 202-961 - APRVL LTR, LBLG, MEDICAL OFFICERS RVWS, ETC
2013-7321	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	JASON SMATHERS MUCKROCK NEWS	DIVESTITURE OF PROHIBITED HOLDINGS
2013-7322	09/12/2013 10/10/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	NATALIA DERIN QUELLER FISHER ET AL	USPS LABS LLC - 483S, RESP, ATTACHMENTS, EXHIBITS, ETC 02/21/12
2013-7323	09/12/2013 10/10/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MACKIE A BARCH PHARMAGEN LABS	PHARMAGEN LABS - CMPLNT
2013-7324	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	COLEEN KLASMEIER SIDLEY AUSTIN LLP	PRESCRIPTION DRUG PROMOTION - TALK PAPER 7/18/91; PFIZER INC - LTR 7/13/82; BRISTO-MYERS SQUIB -

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2013-7325	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WENDY R FLEISHMAN LIEFF CABRASER ET AL	BAYER CORP - ENTERIC COATED ASPIRIN RPTS, INVESTIGATIONS, STATEMENTS, ETC
2013-7326	09/12/2013 10/10/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	HEALTHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	METAGENICS INC - WARNING LTR 8/13/13
2013-7327	09/12/2013 11/04/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Rachel Johnson FOI Services, Inc.	BK120012
2013-7328	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	SBA 20589 S015
2013-7329	09/12/2013 10/10/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Anna Edney BLOOMBERG NEWS	INTUITIVE, SUNNYVALE, CA - 483 01/10/2000 - 09/11/2013
2013-7330	09/12/2013 10/10/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	ROSSMERI MONTALVO ALTUS RESEARCH	SAMUEL LN LEDERMAN MD - EIR, INTERNAL CORR, DETERMINATIONS
2013-7331	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 202379
2013-7332	09/12/2013 10/10/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ELIZABETH BARBEHENN PUBLIC CITIZEN (HEALTH RESEARCH GROUP)	FETZIMA (LEVOMILNACIPRAN) NDA 204-168 APRVL PKG
2013-7333	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anna Edney BLOOMBERG NEWS	INTUITIVE SURGICAL - HOSPITAL AERS 01/01/2000 - 09/11/2013
2013-7334	09/12/2013 10/10/2013	CVM/OCD/	Janice Cacioli LUITPOLD PHARMACEUTICALS, INC.	FOIA SUMMARIES NADA 012-198, NADA 012-204
2013-7335	09/12/2013 10/10/2013	OM/OSS/OPILS/FDAHO/	Katherine Michelle Hardy none	FDA Oral History Interview, Merrill - Part I ABOUT FDA

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2013-7336	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Jane Bentley Alcon Laboratories, Inc.	ALCON CUSI SA, BARCELONA, SPAIN - EIR 09/05/2011 - 09/09/2011
2013-7337	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	CIBA VISION, BATAM, INDONESIA - EIR 05/02/2011 - 05/05/2011
2013-7338	09/12/2013 10/10/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	ALCON GRESHABER, SWITZERLAND - EIR 04/11/2011 - 04/14/2011
2013-7339	09/12/2013 10/10/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Jane Bentley Alcon Labs, Inc.	ALCON LABS, HUNTINGTON, WV - EIR 09/23/2011 - 05/31/2011
2013-7340	09/12/2013 10/10/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jane Bentley Alcon Laboratories, Inc.	CIBA VISION, GROSSWALLASTADT, GERMANY - EIR 06/27/2011 - 08/31/2011
2013-7341	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCRAMP CanReg, Inc.	DAILY LOG 8/19-23/13
2013-7342	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCRAMP CanReg, Inc.	DAILY LOG 8/12-16/13
2013-7343	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/12-16/13
2013-7344	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 8/19-23/13
2013-7345	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/12-16/13
2013-7346	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DRBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/19-23/13
2013-7347	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 8/19-23/13
2013-7348	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW &	DAILY CLOSED LOG 8/12-16/13

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BUSINESS				
2013-7349	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/19-23/13
2013-7350	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/19-23/13
2013-7351	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/12-16/13
2013-7352	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/12-16/13
2013-7353	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 8/12-16/13
2013-7354	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	DAVID MacFARLAND FDA REVIEW/FDA WEBVIEW	DAILY LOG 8/19-23/13
2013-7355	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/19-23/13
2013-7356	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/12-16/13
2013-7357	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/19-23/13
2013-7358	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/12-16/13
2013-7359	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 8/19-23/13
2013-7360	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 8/12-16/13
2013-7361	09/12/2013 10/10/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6078 - REQUEST LETTER
2013-7362	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6445 - REQUEST LETTER ONLY
2013-7363	09/12/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16)	2013-6700 - REQUEST LETTER ONLY

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	10/10/2013		MERCK & CO., INC.	
2013-7364	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/12-16/13
2013-7365	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6606 - REQUEST LETTER ONLY
2013-7366	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6077 - REQUEST LETTER ONLY
2013-7367	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6229 - REQUEST LETTER ONLY
2013-7368	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/19-23/13
2013-7369	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/19-23/13
2013-7370	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/12-16/13
2013-7371	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6243 - REQUEST LETTER
2013-7372	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-5959 - REQUEST LETTER
2013-7373	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6455 - REQUEST LETTER
2013-7374	09/12/2013 10/10/2013	FDA/OC/OES/DFOI/	Joan Stitt (UG2CD-16) MERCK & CO., INC.	2013-6001 - REQUEST LETTER
2013-7375	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Waldran BAYER HEALTHCARE	BAXTER BIODOME, MARSA, MALTA - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013
2013-7376	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Waldran BAYER HEALTHCARE	MEDIMOP MEDICAL PRODUCTS, RAANANA, ISRAEL - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013
2013-7377	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Waldran BAYER HEALTHCARE	BIOFARMITALIA, ITALY - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013
2013-7378	09/13/2013 10/11/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	John Walsh James Alexander Corporation	EMD MILLIPORE CORPORATION, GIBBSTOWN, NJ - EIR, 483, RECALL 09/09/2009 - 09/09/2013
2013-7379	09/13/2013 10/11/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Peter Waldran BAYER HEALTHCARE	VETTER PHARMA FERTIGUNG, RAVENSBURG, GERMANY - EIR, 483, RESPONSES 09/09/2008 - 09/09/2013

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7380	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Peter Waldran BAYER HEALTHCARE	VETTER PHARMA FERTIGUNG, LANGENARGEN, GERMANY - EIR, 483, RESPONSE 09/09/2008 - 09/09/2013
2013-7381	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Shannon McOsker Shannon McOsker	ESSURE - CLINICAL STUDIES
2013-7382	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	John Walsh James Alexander Corporation	AMRESKO, SOLON, OH - EIR, 483, RECALL 09/01/2010 - 09/10/2013
2013-7383	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Robert Mahler Ansell Healthcare Products LLC	NDA 17768
2013-7384	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	John Walsh James Alexander Corporation	APPLIED PLASTICS, OAK CREEK, WI - EIR, 483, RECALL 09/01/2010 - 09/10/2013
2013-7385	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ilya Kister NEW YORK UNIVERSITY MEDICAL CENTER	AZATHIOPRINE - AERS
2013-7386	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jacqueline Coleman Coleman, Jacqueline	ESTRACE VAGINAL CREAM CLINICAL TRIALS INFORMATION 01/01/1984 - 09/10/2013
2013-7387	09/13/2013 10/11/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	DAVID M, PIKE David M. Pike	LIQUID PACKAGING RESOURCES, ATLANTA, GA - 483 01/01/2010 - 09/10/2013
2013-7388	09/13/2013 10/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	DKT 2013-N-0778
2013-7389	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elliot Wilbur WILBUR, ELLIOT	OFFICE OF GENERIC DRUGS STATISTICAL REPORT - MOST RECENT

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2013-7390	09/13/2013 10/11/2013	FDA/OF/CFSAN/OCD/EOS/	A Philip Leber A Philip Leber Consulting	FCN 1251
2013-7391	09/13/2013 10/11/2013	ORA/ ORA/ FDA/OGROP/ORA/ORO/DIOP/ ORA/ORM/ ORA/ORM/ ORA/ORM/ ORA/ORM/	Patrick Woodall Food & Water Watch	FDA FISH, FISHERY, AND SEAFOOD IMPORT INSPECTION, LABORATORY TESTING AND TOTAL IMPORT LINES OF ENTRY FOR FDA PRODUCT CODE 16
2013-7392	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Caj Boatright ARNOLD & ITKIN LLP	ZOLOFT - RECS RE BIRTH DEFECTS AND PREGNANCY
2013-7393	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	TAKEDA, SINGEN, GERMANY - EIR, 483 1/1/07 TO PRESENT
2013-7394	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	BLA 125320 007
2013-7395	09/13/2013 10/11/2013	ORA/ ORA/ ORA/ORM/ ORA/ORM/ FDA/OF/CFSAN/OCD/EOS/	Rend Al-Mondhiry COUNCIL FOR RESPONSIBLE NUTRITION	LIST OF FACILITIES RE DIETARY SUPPLEMENT OR COMPONENT OF DIETARY SUPPLEMENT
2013-7396	09/13/2013 10/11/2013	ORA/ ORA/ FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/ FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Gitte Laasby MILWAUKEE JOURNAL SENTINEL	CHOBANI - LAB TEST RESULTS SUBMITTED TO FDA
2013-7397	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	Christopher Brennan WESTLAW COURT EXPRESS	JANUVIA, JANUMET - FOIA REQUESTS AND RECORDS

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2013-7398	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Golnaz Moeini STRYKER CORP	K091515
2013-7399	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	Carolyn Wolski Michael Foods, Inc.	MICHAEL FOODS, INC, ELIZABETH, NJ - RECS RE OUTBREAK REPORT : 05/15/2010 - 08/15/2010
2013-7400	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	shin kang WELLS FARGO	GILEAD SCIENCES - 483, EIR 01/01/2013 - 09/12/2013
2013-7401	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. Eugene Guthery, M. D. INNOVATIVE PHARMACEUTICALS, LLC	NDA 022055
2013-7402	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. Eugene Guthery, M. D. INNOVATIVE PHARMACEUTICALS, LLC	IND 66095
2013-7403	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Jennifer Newberger Hyman, Phelps & McNamara P.C.	CORR BETWEEN FDA AND MANUFACTURERS OR DISTRIBUTORS OF PERSONAL SOUND AMPLIFICATION PRODUCTS RE SALE OF THOSE PRODUCTS 06/01/2012 - 09/13/2013
2013-7404	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. Eugene Guthery, M D. Innovative Pharmaceuticals,LLC	IND FOR XF-73
2013-7405	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	Doe J	DEPUY - HIP IMPLANTS MDRS
2013-7406	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	AMY GAITHER LATHAM & WATKINS LLP	KARMELSONIX - WIM PC MODEL 1010 K071955
2013-7407	09/13/2013 10/11/2013	FDA/OMPT/CDRH/OCER/DFOI/	PAUL SVILANS JOHNSON WINTER ET AL	BORN BRANDS - BABY WEDGE MTGS, WARNINGS
2013-7408	09/13/2013 10/11/2013	FDA/OGROP/ORA/SE-FO/ATL- DO/ATL-CB/	David Green CIBA VISION Corporation	CIBA VISION CORPORATION, DULUTH, GA - EIR 09/01/2012 - 09/01/2013

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2013-7409	09/13/2013 10/11/2013	FDA/OF/CFSAN/OCD/EOS/	LISA Y. LEFFERTS CENTER FOR SCIENCE IN THE PUBLIC INTEREST	CAFFEINE ADDED TO FOOD AND DRINKS - GRAS, CORR
2013-7410	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	GARDNER, JEFFREY	PERSONALIZED PROTEIN POWDER
2013-7411	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	DAWN M. CHITTY TORRENT PHARMA INC	POTIGA (EZOGABINE) NDA 22-345
2013-7412	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/CIN- DO/CIN-CB/	PAUL B. CALLAHAN CHARLES RIVER LABS	CHARLES RIVER LABORATORIES INC, SPENCERVILLE, OH - EIR 10/30/12-11/15/12
2013-7413	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID M. HOFFMEISTER WISLON SONSINI ET AL	COPAXONE NDA 20-622/S083, S085; ADRENALIN NDA 20-800/S023 - SBA
2013-7414	09/13/2013 10/11/2013	FDA/OC/OES/DDM/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	B. KRISTIAN W. RASMUSSEN CORY WATSON ET AL	NEXIUM (ESOMEPRAZOLE) - APRVL, RVWS, CORR, WARNINGS
2013-7415	09/13/2013 10/11/2013	FDA/OGROP/ORA/CE-FO/BLT- DO/BLT-CB/	DIANNE L. CHAMBERS HOGAN LOVELLS LLP	McCORMICK & COMPANY, HUNT VALLEY, MD - EIR MOST RECENT
2013-7416	09/13/2013 10/11/2013	FDA/OF/CFSAN/OCD/EOS/	EMILY K. STRUNK AKIN GUMP ET AL	PROCESADORA DE PRODUCTOS MARINOS DELIFISH SA, PUERTO MONTT, CHILE - LAB RPTS, ANALYTICAL W/S, EIR, ETC
2013-7417	09/13/2013 10/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-7418	09/13/2013 10/11/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-7419	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	Doe J	USE OF EMPLOYEE EDUCATION & TRAINING
2013-7420	09/13/2013 10/11/2013	ORA/ORM/ ORA/ORM/	KIM C. CAPONE PORZIO LIFE SCIENCES	PDMA 2008 TO PRESENT
2013-7421	09/13/2013 10/11/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	FORD, LISA	ROSEMONT FARMS, PLANT CITY, FL - INSP

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2013-7422	09/13/2013 10/11/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	CARLO CASULO, MD ASCEND CAPITAL LLC	AMPIO - AMPION TYPE B PRE-BLA MTG MINS 10/29/13, LTR 9/6/13
2013-7423	09/13/2013 10/11/2013	FDA/OC/OES/DFOI/	GARDNER, JEFFREY	2012-2202, 2012-2938, 2012-6232, ETC
2013-7424	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Anne Mitchell Anne Mitchell	CPT1300384 - CORR
2013-7425	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Astrid Marx Heraeus Medical GmbH	K112470
2013-7426	09/16/2013 10/15/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	Sylvia Hinds Hinds, Sylvia L	ALLIANCE MEDICAL PRODUCTS, INVINE, CA - EIR, 483 09/01/2011 - 09/13/2013
2013-7427	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Seth Miller Cubist Pharmaceuticals	NDA 050706
2013-7428	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Golnaz Moeini STRYKER CORP	K101077
2013-7429	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Steven Yu Ryuh Biomedical Research Foundation	NDA 020505 - OLD LABEL INFO
2013-7430	09/16/2013 10/15/2013	FDA/OF/CFSAN/OCDE/EO/	Danny Robbins Atlanta Journal-Constitution	DIETARY SUPPLEMENTS CONTAINING DMAA - AERS
2013-7431	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K122356
2013-7432	09/16/2013 10/15/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-1209
2013-7433	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NDA 22334 S 016

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7434	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ilya Kister NEW YORK UNIVERSITY MEDICAL CENTER	GLATIRAMER - AERS
2013-7435	09/16/2013 10/15/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Carol L. Price Carol L. Price	DAVINCI ROBOTIC SURGICAL DEVICE - COMPLAINTS RE DEVICE AT CITY OF HOPE HOSPITAL, DUARTE, CA 01/01/2000 - 09/10/2013
2013-7436	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K121678
2013-7437	09/16/2013 10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	George Hwang EOS Pharmaceutical Corp.	NORVIR 80 MG/ML ORAL SOLUTION - APPROVAL LETTER, LABELING, CMC ETC
2013-7438	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	AnnaMarie Daniels AnnaMarie Daniels	K081465 K123338 K131475 ETC
2013-7439	09/16/2013 10/15/2013	FDA/OC/OES/DDM/	Lael J Pickett Lael J Pickett	ORTHOPEDICS AND REHABILITATION DEVICES ADVISORY PANEL - TRANSCRIPT 11/20/1996 - 11/20/1996
2013-7440	09/16/2013 10/15/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/ FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	JOSEPH R. WARNHOFF PERFORMANCE PRODUCTS, INC.	PERFORMANCE PRODUCTS, INC, ST LOUIS, MO - INTERNAL REPORTS RE INSPECTIONS 01/01/2011 - 08/01/2013
2013-7441	09/16/2013 10/15/2013	FDA/OC/OES/DFOI/	Robert FDANEWS	FOIA DISCLOSURE LOG 09/09/2013 - 09/13/2013
2013-7442	09/16/2013 10/15/2013	FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	Jeff Peterson Ater Wynne LLP	YOCREAM INTERNATIONAL, INC, PORTLAND, OIR - INSPECTION RECS, ENFORCEMENT ACTIONS, CONTRACT INSPECTIONS ETC 01/01/2007 - 09/13/2013
2013-7443	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	Hummad Tasneem University of Memphis	K052155
2013-7444	09/16/2013 10/15/2013	ORA/ORM/ ORA/ORM/	David Mangione Govzilla, Inc.	LIST OF INSPECTIONS 08/1713 - 09/15/2013
2013-7445	09/16/2013	FDA/OMPT/CDER/GRP/DIDP/		INDIVIDUAL RECS

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	10/15/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	
2013-7446	09/16/2013 10/15/2013	FDA/OMPT/CDRH/OCER/DFOI/	VLK BAJNATH ARTHREX INC	MW#5031363 - FACILITY NAME, TELEPHONE NUMBER
2013-7447	09/16/2013 10/15/2013	FDA/OGROP/OIP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WILLIAM J DUBANEVICH PARKER & WAICHMAN ATTYS	AMYLLIN PHARMACEUTICALS LLC, ELI LILLY & CO, MERCK SHARP & DOHME CORP, ETC - GLP-1 BASED DIABETES THERAPIES CORR, AERS 1/1/00 TO 9/11/13
2013-7448	09/16/2013 10/15/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/ FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	WILLIAM A GARVIN BUCHANAN INGERSOL PC	BOCA PHARMACAL INC, QUALITEST PHARMS - 483S WARNING LTRS 1/12 TO PRESENT
2013-7449	09/16/2013 10/15/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	paul hopper Nucleus Therapeutics	MEDCLONE - PHASE 1 IND
2013-7450	09/16/2013 10/15/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Bruce Ricigliano VP of Operations American Lifestyle American Lifestyle	VICEREX - INVESTIGATION RECS (04/29/2013 - 05/08/2013)

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OF/CFSAN/OCD/EOS/		
2013-7451	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	response/memo sent by leslie ball or other dsi personnel in response to I3938 OIG/HHS
2013-7452	09/17/2013 10/30/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	Jason Ahlmann Zija International, Inc.	ZIJA INTERNATIONAL INC - INVESTIGATION RECS (01/16/2005 - 09/16/2013)
2013-7453	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	Most recent QAP for Novartis in Emeryville, CA
2013-7454	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	Most recent QAP for Novartis in Emeryville, CA
2013-7455	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	QAP information 2007-present for Novartis, Emeryville, CA
2013-7456	09/17/2013 10/30/2013	FDA/OO/OFBA/OAGS/	Kenneth A. Horton Managed Care of Western New York, d/b/a Probe Services	13-223-SOL-00173
2013-7457	09/17/2013 10/30/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	CAP 3C0198
2013-7458	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joseph P. Reo Merck Consumer Care	DITROPAN IMMEDIATE RELEASE TABLET 5 MG - HUMAN CLINICAL TRIALS, PHARMACOLOGY 06/01/1975 - 07/30/1975
2013-7459	09/17/2013 10/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K113700
2013-7460	09/17/2013 10/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	LYNN SHEPLER Self	C6 TESTING DATA SEX DIFFERENCES RE LYME DISEASE 09/01/2003 - 09/16/2013

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		FDA/OMPT/CDRH/OCER/DFOI/		
2013-7461	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA22406 S1, S2, S3
2013-7462	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	ANDA 76477
2013-7463	09/17/2013 10/30/2013	FDA/OF/CFSAN/OCD/EOS/	Philip Leber A. Philip Leber Consulting	FCN1282
2013-7464	09/17/2013 10/30/2013	FDA/OF/CFSAN/OCD/EOS/	Philip Leber A. Philip Leber Consulting	FCN1237
2013-7465	09/17/2013 10/30/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	CARLA R SCARMAZZI King & Spalding LLP	CHOBANI GREEK YOGURT - CMLPNTS 8/2/13 TO PRESENT
2013-7466	09/17/2013 10/30/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	HEWLETT, IRIS	SAN MATEO MEDICAL CENTER RADIOLOGY DEPT, SAN MATEO, CA - QUALITY CONTROL EVALUATIONS, ANNUAL INSPS, TEST RESULTS, ETC 2001 TO 7/13
2013-7467	09/17/2013 10/30/2013	CVM/OCD/	KRISTI O SMEDLEY PHD Center for Regulatory Services, Inc.	METAL METHIOMINE HYDROXY ANALOGUE - SUBMISSION, CORR
2013-7468	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ROWENA DODARO ALKERMES GAINESVILLE L LLC	VIVITROL - ISRS 8738905, 8583821
2013-7469	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CAUDLE #20711-058, BRANDON LEE	TRUVADA, PREZISTA, NORVIR - PI
2013-7470	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SAMUEL F COLIN MD FIRST MANHATTAN CO	VICTOZA (LIRAGLUTIDE) - AERS 2/10 TO PRESENT

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2013-7471	09/17/2013 10/30/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDRH/OCER/DFOI/	LYNN SHEPLER Self	ISPOY LYME TEST - DATA SUBMITTED 09/01/2010 - 09/17/2013
2013-7472	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Jeannie Lin Route One Investment Company	AGILA SPECIALTIES - WARNING LETTER 06/27/2013 - 09/16/2013
2013-7473	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nirav Jhaveri Jhaveri, Nirav	AGILA INJECTIBLES - WARNING LETTER 09/15/2013 - 09/16/2013
2013-7474	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Ted Keller Sigma Capital Management	STRIDES ARCOLABL INJECTIBLE (AGILA SPECIALTIES) - WARNING LETTER, 483 05/31/2013 - 09/30/2013
2013-7475	09/17/2013 10/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	Natalie Mink KARL STORZ Endoscopy America, Inc.	KARL STORZ GMBH & CO KG, TUTTLINGEN, GERMANY - EIR 10/15/12
2013-7476	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Ulrike Domack EXDRA GmbH	NDA004782-S141 - BIOEQUIVALENCE STUDY; NDA004782-S142 - BIOEQUIVALENCE STUDY
2013-7477	09/17/2013 10/30/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	Buddy Keeley Seafood Supply Company	DALLAS DISTRICT SEAFOOD INSPECTION RECS 01/01/2011 - 09/01/2013
2013-7478	09/17/2013 10/30/2013	CVM/OCD/	Kelly Perfield Elanco Animal Health - Kelly Perfield	N-140872-R-0265
2013-7479	09/17/2013 10/30/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID GORTLER, PHARM.D., FCCP GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE	MEDWATCH RECS RE ZOLOFT
2013-7480	09/17/2013 10/30/2013	FDA/OC/OES/DFOI/	Chirag Talati Espirito Santo Securities	RANBAXY - 483, EIR SINCE MARCH 2013
2013-7481	09/17/2013	FDA/OC/OES/DFOI/	Esther Farber	2011-5064, 2012-2367, 2012-4606 ETC

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	10/30/2013		Labaton Sucharow, LLP	
2013-7482	09/17/2013 10/30/2013	FDA/OC/OES/DFOI/	Jaime Vassallo LexisNexis CourtLink Document Retrieval	2013-2536
2013-7483	09/18/2013 10/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jennifer Panagoulas GENZYME	Form 483 issued to Dragana Obradovic, MD Military Medical Academy, Belgrade, Serbia
2013-7484	09/18/2013 10/17/2013	FDA/OC/OES/DFOI/	Jennifer Panagoulas GENZYME	Form 483 issued to Tomasz Zielinski, MD, Diagnomed Clinical Research UI Lesnego Potoku, 40-414 Katowice Poland
2013-7485	09/18/2013 10/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Jennifer Panagoulas GENZYME	Form 481 issued to Karl Baum, MD, Heningsdorf, Germany
2013-7486	09/18/2013 10/17/2013	FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	Information for 3 tobacco studies
2013-7487	09/18/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/	Kim Carson EXPONENT	DECAFFEINATED TEAT - LABELING POLICY 01/01/1980 - 01/01/1990
2013-7488	09/18/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/	Kim Carson EXPONENT	DECAFFEINATED COFFEE - LABELING POLICY 01/01/1980 - 01/01/1990
2013-7489	09/18/2013 10/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Cathy Burgess ALSTON & BIRD LLP	STRIDES ARCOLAB - WARNING LETTER 06/01/2013 - 09/17/2013
2013-7490	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	John Fesko Fesko, John D	P10020, P110012, P110030
2013-7491	09/18/2013 10/17/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Paul Nemeth iCeutica Operations, LLC	ZACH SYSTEMS, SA, AVRILLE CEDEX, FRANCE - INSPECTION REPORT 01/01/2006 - 06/30/2013
2013-7492	09/18/2013 10/17/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Tina Ball Barnhardt Manufacturing Company	BARNHARDT MANUFACTURING COMPANY, CHARLOTTE, NC - EIR 12/12/2011 - 12/14/2011
2013-7493	09/18/2013	FDA/OF/CFSAN/OCD/EOS/	John Hnatio	FOODQUEST TQ LLC - 351 EMAILS RE MEMORANDUM 05/20/2013 - 08/21/2013

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	10/17/2013		FoodQuestTQ LLC	
2013-7494	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NDA Approval summary (SBA) for TOKENDI XR, NDA 201635 Tian, Wendy	NDA 201635 - SBA
2013-7495	09/18/2013 10/17/2013	FDA/OF/CFSAN/OCD/EOS/	Joe Hain Bryant Christie Inc.	CALCIUM STEAROLYN-2-LACTYLATE - SAFETY AND CHEMISTRY DATA
2013-7496	09/18/2013 10/17/2013	FDA/OMPT/CTP/OD/	Brady Dennis THE WASHINGTON POST	LIST OF LISTENING SESSION MEETINGS THAT CTP HAS HAD WITH ANY REPRESENTATIVES OF THE E-CIGARETTE INDUSTRY 09/01/2012 - 09/17/2013
2013-7497	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Paul Nemeth iCeutica Operations, LLC	OLON SPA, RODANO, ITALY - INSPECTION REPORTS FOR DRUG QUALITY ASSURANCE 01/02/2006 - 06/28/2013
2013-7498	09/18/2013 10/17/2013	FDA/OC/OES/DFOI/	Heather Corwin-Smith or Sherry Anne Lear Law Offices of Sherry Anne Lear	IRENDA COPORATION - WARNING LETTER (CERTIFIED) 04/15/2013 - 04/15/2013
2013-7499	09/18/2013 10/17/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	Tim Farber Astellas Pharm Global Development, Inc.	GENENTECH, SAN FRANCISCO, CA - EIR 08/01/2012 - 08/01/2013
2013-7500	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Chirag Talati Espirito Santo Securities	WOCKHARDT - EIR, 483 01/01/2011 - 09/18/2013
2013-7501	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	DR. RAJIV VARMA SAFE OBSTETRIC SYSTEMS LTD	MILEX PRODUCTS INC - INFLAT O BALL K904026
2013-7502	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Meghan C. Lewallen Mellino Robenalt, LLC	SCOPOLAMINE - ADVERSE EVENT REPORT
2013-7503	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	DR RAJIV VARMA SAFE OBSTETRIC SYSTEMS LTD	BIOTEQUE AMERICA INC - INFLATABLE PESSARY K092981
2013-7504	09/18/2013 10/17/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID DAVIS PUBLIC CITIZEN	ARICEPT (DONEPEZIL) NDA 20-690/S2-037; 21-720/S-010; 22-568/S-007

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7505	09/18/2013 10/17/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	MERYL NASS MD MOUNT DESEA ISLAND HOSPITAL	ANTHRAX VACCINE - SAFETY INFORMATION FROM TRIALS 2002 TO 2007; VAERS
2013-7506	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/	DOBSON, DONALD MARK .	AGREEMENT BETWEEN FDA, MEDTRONIC & WARSAW ORTHOPEDIC CO
2013-7507	09/18/2013 10/17/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/ FDA/OMPT/CDRH/OCER/DFOI/	NICOLE STARK ESQ	SEPRAFILM RECALL
2013-7508	09/18/2013 10/17/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ ORA/ ORA/	SAMANTHA MYERS ROANOKE CLAIMS SERVICES	SUPER PAN BAKERY INC - ENTRY NO ESD00450715
2013-7509	09/18/2013 10/17/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	GADDIE, DEBORAH	RESTATSIS - AERS
2013-7510	09/18/2013 10/17/2013	FDA/OC/OES/DFOI/	Jeannie Lin Route One Investment Company	WOCKHARDT, INDIA - 483 07/01/2013 - 08/16/2013
2013-7511	09/19/2013 10/18/2013	FDA/OMPT/OSMP/OOPD/	Deborah Casso EpiSource	Orphan drug application and any resulting correspondence for Kcentra (Proper name: Prothrombin Complex Concentrate, Human)
2013-7512	09/19/2013 10/18/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	SABILA SRL - CORR WITH FDA RE WARNING LETTER 7/1/13
2013-7513	09/19/2013 10/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	Spring Miranda Philips Medical Systems (Cleveland), Inc.	K131576
2013-7514	09/19/2013 10/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Alan Katz BLOOMBERG NEWS	NDA 050733-035 LABELING
2013-7515	09/19/2013 10/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joshua A. Klarfeld ULMER & BERNE LLP	SSRI - AERS, CATEGORIZATION RECS, ETC

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7516	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	ZITTKOWAKI	POPULATION GROWTH - INVENTORY, CATALOG, SUMMARIES 2009 TO PRESENT
2013-7517	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	KLEN REID WASHINGTON INFORMATION SOURCE	PRINTOUT OF ALL CLOSED FOIA FOR EIRS & 483S 1/13 TO PRESENT
2013-7518	09/19/2013 10/18/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	LIVING ESSENTIALS - 5 HOUR ENRGY; PEPSI CO INC - AMP ENERGY; CELSIUS HOLDINGS INC, GLIF SHOT GEL ETC - CORR 2/13/13 TO PRESENT
2013-7519	09/19/2013 10/18/2013	FDA/OF/CFSAN/OCD/EOS/	MARILYNN WHITNEY COVINGTON & BURLING LLP	COCA-COLA CO - NOS DRINK & VITAMIN WATER ENERGY CONTAINING ADDED CAFFEINE LTRS 8/1/13, 6/3/13
2013-7520	09/19/2013 10/18/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	LESLIE SANDS LUPIN PHARMACEUTICALS INC	ASTELLAS PHARMA US INC - ASTAGRAF XL (TACROLIMUS ER CAPS) NDA 204-096 SBA
2013-7521	09/19/2013 10/18/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	LINDSAY A ABRAHAM WESTERN INSTITUTIONAL REVIEW BOARD	SCANTIBODIES BIOLOGICS INC, EL CAJON, CA; SCANTIBODIES LABORATORY INC, SANTEE, CA - EIRS, 483S, 482S, ETC 3/13 TO 5/13
2013-7522	09/19/2013 10/18/2013	FDA/OMPT/CDRH/OCER/DFOI/	BARRY MEIER NEW YORK TIMES	BSD-2000 INTERNAL DISPUTE RESOLUTION MTG MEMOS, RPTS, RECS
2013-7523	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	AIMEE JOHNSON FULBRIGHT & JAWORSKI LLP	NEVADA PUBLIC RECORDS DECLARATION - RECS (CERTIFIED)
2013-7524	09/19/2013 10/18/2013	FDA/OC/OES/DFOI/	DEBORAH K DODGE HALL ANSLEY RODGERS ET AL	LETTERMAN FEED - CMPNT 115361
2013-7525	09/19/2013 10/18/2013	FDA/OF/CFSAN/OCD/EOS/	SUSAN B CASPER PROPER COURSE INC	US INFANT FORMULA - LIST OF FIRMS NOT IN CHINA
2013-7526	09/20/2013 10/21/2013	FDA/OMPT/CTP/OD/	Kyle Rozema Cornell University	QUANTITIES OF MENTHOL IN EACH CIGARETTE - PUBLISHED LIST
2013-7527	09/20/2013 10/21/2013	FDA/OC/OES/DFOI/	Rachel Johnson FOI Services, Inc.	2013-6279
2013-7528	09/20/2013 10/21/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	David Kim Partner Fund Management	RANBAXY LABORATORIES LIMITED, INDIA, NEW JERSEY - 483 01/03/2012 - 09/19/2013

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2013-7529	09/20/2013 10/21/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karen Schultz The Dominion Group	ANDA 202580
2013-7530	09/20/2013 10/21/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	MCKENZIE E CATO Hyman, Phelps & McNamara P.C.	ACTIN BIOMED, ARCHER BIOSCIENCES, FORESIGHT BIOTHERAPEUTICS - RPTS, SUMMARIES, INVESTIGATION RECS, ETC 2009 TO PRESENT
2013-7531	09/20/2013 10/21/2013	FDA/OC/OES/DFOI/ FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	MARY STIPANCIC PHARMA MEDICA RESEARCH INC	GATEWAY MEDICAL RESEARCH (CETERO/PRACS), ST CHARLES, MO - 483, CO RESP 1/03 TO 4/13
2013-7532	09/20/2013 10/21/2013	FDA/OF/CFSAN/OCD/EOS/	VINCENT RABOTEAU Center For Food Safety	REMOVAL OF POLLEN FROM HONEY, FILTRATION, ULTRA-FILTRATION & DEFINITION OF HONEY, ETC - RECS
2013-7533	09/20/2013 10/21/2013	FDA/OMPT/CTP/OD/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	DISTRIBUTOR, RETAILER, MFR OF TOBACCO PRODS - CORR, RECS
2013-7534	09/20/2013 10/21/2013	FDA/OC/OES/DDM/	MARK E GREENWOLD CAMPAIGN FOR TOBACCO-FREE KIDS	DKT 2012N-0212
2013-7535	09/20/2013 10/21/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/ ORA/ ORA/	HUFFMAN, RAY	CMPLNT 131441
2013-7536	09/20/2013 10/21/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	JANIS WILSON GRIFOLS INC	SOURCE PLASMA LICENSED FACILITIES - IND STUDY PROTOCOLS FOR IMMUNIZATION PROGRAMS THAT STUDIED THE SAFETY OF DONORS WHO RECEIVED VACCINE INJECTIONS
2013-7537	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	BONOS R PMMA BONE CEMENT - K123225
2013-7538	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	DEPUY - CMW1, CMW2, CMW3 BONE CEMENT K053003
2013-7539	09/20/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD	DEPUY - CMW 1 GENTAMICIN BONE CEMENT K053002

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	10/21/2013		CARDINAL HEALTH	
2013-7540	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	LAVENIA FORD CARDINAL HEALTH	BONOS R GENTA PMMA BONE CEMENT - K123081
2013-7541	09/20/2013 10/21/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID DAVIS HOVERTECH INTERNATIONAL	DT DAVIS ENTERPRISES LTD (HOVERTECH INTERNATIONAL) - HOVERTRANS TRANSFORMER MODEL HTT-650P K102236
2013-7542	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Maria Merchant Somnarus Inc	K121319, K113862
2013-7543	09/23/2013 10/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Tonya Hatton Grifols Plasmacare	GRIFOLS PLASMACARE, TERRE HAUTE, IN - 482, EIR (01/01/2011 - 12/31/2011)
2013-7544	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Marco Manduchi Thema s.r.l.	K121418
2013-7545	09/23/2013 10/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	PFIZER, ROCHESTER, MI - EIR 11/13/2012 - 12/13/2012
2013-7546	09/23/2013 10/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker MORGAN LEWIS & BOCKIUS LLP	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - 483 05/07/2012 - 05/10/2012
2013-7547	09/23/2013 10/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	FORMOSA LABORATORIES, TAOYUAN, TAIWAN - EIR (05/07/2012 - 05/10/2012)
2013-7548	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Travis Siverson BIRCHWOOD LABORATORIES INC	OH SO CLEAN, INC, SAN FRANCISCO, CA - RESPONSES, CORRECTIVE ACTION, ETC 09/01/2010 - 07/19/2012
2013-7549	09/23/2013 10/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Deborah Sontag THE NEW YORK TIMES	BUPRENORPHINE ADDICTION PRODUCTS - AERS 03/11/2013 - 09/20/2013
2013-7550	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K032222
2013-7551	09/23/2013 10/22/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Timothy A. Kolaya Greenberg Traurig, P.A.	ANDA 077656, ANDA 077658

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7552	09/23/2013 10/22/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Rebecca Dandeker Morgan, Lewis & Bockius LLP	PFIZER, INC, ROCHESTER, MN - EIR 06/11/2012 - 06/15/2012
2013-7553	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	alex russell Asta Fluidic Technologies, Inc.	K990641, K892241, K071652
2013-7554	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Ben Joseph Rice Voelker	FDA, MEDSUUN, INTUTIVE SURGICAL - CORR RE SMALL SAMPLE SURVEY OF DA VINCI SURGICAL SYSTEM 05/01/2013 - 09/20/2013
2013-7555	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	Thomas Hwang HARVARD UNIVERSITY	PMA WTIH APPROVED PEDIATRIC SUBPOPULATIONS FOR 2012 01/01/2012 - 12/31/2012
2013-7556	09/23/2013 10/22/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION SOURCE	GLUTATHIONE CORP, ELMSFORD, NY - 483, CO RESP WARNING LTR, ETC 9/12 TO 10/12
2013-7557	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACCLARENT, MENLO PARK, CA - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7558	09/23/2013 10/22/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MEGA SUN INC, ST LOUIS, MO - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7559	09/23/2013 10/22/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	AGNESIAN HEALTHCARE, FOND DU LAC, WI - 483, CO RESP, WARNING LTR, ETC 11/12
2013-7560	09/23/2013 10/22/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOCOMPATIBLES INC, OXFORD, CT - 483, CO RESP, WARNING LTR, ETC 2/13 TO 4/13
2013-7561	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	OLYMPIA WOMEN'S HEALTH, OLYMPIA, WA - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7562	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	HOSPIRA HEALTHCARE INDIA, ARIPERUMBURDUR, INDIA - 483, CO RESP, WARNING LTR, ETC 10/12
2013-7563	09/23/2013	FDA/OGROP/ORA/PA-FO/SEA-	KEN REID	PUGET SOUND BLOOD CENTER, SEATTLE, WA - 1/13 TO

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	10/22/2013	DO/SEA-CB/	WASHINGTON INFORMATION SOURCE	2/13
2013-7564	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN RIED WASHINGTON INFORMATION SOURCE	FINEMOST CORP, CERRITOS, CA - 483, CO RESP, WARNING LTR 9/12
2013-7565	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALEXION PHARMACEUTICALS, CHESHIRE, CT - 483, CO RESP, WARNING LTR, ETC 7/12 TO 8/12
2013-7566	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MICHAEL RING MD, SPOKANE, WA - 483, CO RESP. WARNING LTR, ETC 7/12 TO 8/12
2013-7567	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AMRESKO, SOLON, OH - 483, CO RESP WARNING LTR, ETC 10/12 TO 12/12
2013-7568	09/23/2013 10/22/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AIONEX, GOODLETTSVILLE, TN - 483, CO RESP WARNING LTR, ETC 11/12
2013-7569	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACELL INC, COLUMBIA, MD - 483, CO RESP, WARNING LTR, ETC 11/12 TO 12/12
2013-7570	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AUTOMATED OPHTHALMICS, COLUMBIA, MD - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7571	09/23/2013 10/22/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	EDWARDS LIFESCIENCES, DRAPER, UT - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7572	09/23/2013 10/22/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN RIED WASHINGTON INFORMATION SOURCE	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC, MINERAL WELLS, TX - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7573	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	K S CHOI CORP, LOS ANGELES, CA - 483, CO RESP, WARNING LTR, ETC 12/12 TO 2/13
2013-7574	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	RIVERPOINT MEDICAL, PORTLAND, OR - 483, CO RESP, WARNING LTR, ETC 1/13 TO 2/13
2013-7575	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION	VALLEY HEALTH WINCHESTER MEDICAL CENTR IRB, WINCHESTER, VA - 483, CO RESP WARNING LTR, ETC 1/13

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			SOURCE	TO 2/13
2013-7576	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CISPHARMA, CRANBURY, NJ - 483, CO RESP, WARNING LTR, ETC 3/12 TO 4/12
2013-7577	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALMA LASERS INC, BUFFALO GROVE, IL - 483, CO RESP, WARNING LTR, ETC 1/13
2013-7578	09/23/2013 10/22/2013	FDA/OGROP/ORAPA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALPHA MEDICAL INSTRUMENTS, MISSION VIEJO, CA - 483, CO RESP, WARNING LTR, ETC 12/12 TO 1/13
2013-7579	09/23/2013 10/22/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION SOURCE	TRANSONIC SYSTEMS INC, ITHACA, NY - 483, CO RESP, WARNING LTR, ETC 2/13 TO 3/13
2013-7580	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/DET-DO/DET-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMEDIX INC, BLOOMINGTON, IN - 483, CO RESP, WARNING LTR 2/13 TO 3/13
2013-7581	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	shin kang WELLS FARGO	KALYDECO, JAKAFI, TECFIDERA, ETC - AERS 07/01/2013 - 09/30/2013
2013-7582	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Neil Malhotra Malhotra, Neil	CM-AT - EFFICACY, ADVERSE EVENTS 09/01/2010 - 09/23/2013
2013-7583	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDRH/OCER/DFOI/	HUES, TOLEDO .	COAPT SYSTEMS - NOVELLE GEL CLNCL TRIALS, AER
2013-7584	09/23/2013 10/22/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	NPS PHARMACEUTICALS - GATTEX FAERS, EIR, 483, UNTITLED LTRS

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2013-7585	09/23/2013 10/22/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	AEGERION PHARMACEUTICALS INC - JUXTAPID (LOMITAPIDE) AER, EIR, 483, UNTITLED LTRS
2013-7586	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	ISIS PHARMACEUTICALS INC - 483, EIR, UNTITLED LTRS 1/13 TO PRESENT
2013-7587	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	ANDREW HACK, MD, PhD. MILLENNIUM MANAGEMENT LLC	SEATTLE GENETICS INC - EIR, 483, UNTITLED LTRS 4/13 TO PRESENT
2013-7588	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	THERAPEUTICS INC - EIR, 483, UNTITLED LTRS 1/10 TO PRESENT
2013-7589	09/23/2013 10/22/2013	FDA/OC/OES/DFOI/	Robert King FDANEWS	FOIA REQUEST LOG 09/16/2013 - 09/20/2013
2013-7590	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DAVID LOHMAN MILLENNIUM MANAGEMENT LLC	DEPOMED - GRALISE (GABAPENTIN) FAERS, UNTITLED LTRS 1/11 TO PRESENT
2013-7591	09/23/2013 10/22/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	JENNIFER HSIEH DEERFIELD INSTITUTE	BIOGEN IDEC INC - 483
2013-7592	09/23/2013 10/22/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	BRENDA M. GARTZ ELI LILLY & CO	DYAX CORP, CAMBRIDGE, MA - 483 7/11
2013-7593	09/23/2013 10/22/2013	ORA/ ORA/	KYRIAKIDIS., JOANNA	AMERIDOSE LLC, WESTBOROUGH, MA - EIR
2013-7594	09/23/2013 10/22/2013	ORA/OCI/ ORA/OCI/	Doe J	INDIVIDUAL RECS
2013-7595	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	RITALIN - AER
2013-7596	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Doe J	MEDWATCH RPT

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2013-7597	09/23/2013 10/22/2013	FDA/OO/OFBA/OAGS/	DAVID S. NALVEN HAGANS BERMAN ET AL	ASTELLAS PHARMA INC - PROGRAF (TACROLIMUS) DOCS
2013-7598	09/23/2013 10/22/2013	FDA/OF/CFSAN/OCD/EOS/	FRANCIS, ANA	LTR FROM UNITED TO FDA
2013-7599	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MICHAEL S. HEYL HOGAN LOVELLS LLP	IVERA MEDICAL CORP - INVESTIGATIONS
2013-7600	09/23/2013 10/22/2013	FDA/OGROP/ORA/CE-FO/PHI- DO/PHI-CB/	APRIL M. BIGGS THOMAS THOMAS & HAFFER	GPR CO, ROYERSFORD, PA - INVESTIGATIONS, CORR
2013-7601	09/23/2013 10/22/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	PATRICK KELLY CONWAY, HOMER & CHIN- CAPLAN PC	INDIVIDUAL RECS
2013-7602	09/23/2013 10/22/2013	FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JENNIFER A. HYLEMON MORRISON MAHONEY LLP	ENDO WRIST HOT SHEARS - RECALL
2013-7603	09/23/2013 10/22/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	WARREN WILLIAMS FOREST RESEARCH INSTITUTE	AMITIZA (LUBIPROSTONE) NDA 21-908/S-011 APRVL
2013-7604	09/23/2013 10/22/2013	FDA/OMPT/CDRH/OCER/DFOI/	SANDY MASTROIANNI ITC	PRO TIME - MICROCOAGULATION SYS K961835
2013-7605	09/23/2013 10/22/2013	FDA/OC/OES/DFOI/	SKERTIC, MARK	2006-9732, 2008-7899, 2012-6322 ETC
2013-7606	09/24/2013 10/23/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	HAIR LABS INC, NASHVILLE, TN - 483, CO RESP, WARNING LTR, ETC 4/13
2013-7607	09/24/2013 10/23/2013	FDA/OGROP/ORA/NE-FO/NWE- DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CONAIR CORP, STAMFORD, CT - 483, CO RESP, WARNING LTR, ETC 5/13
2013-7608	09/24/2013 10/23/2013	FDA/OGROP/ORA/SW-FO/KAN- DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LIFESERVE BLOOD CENTER, DES MOINES, IA - 483, CO RESP, WARNING LTR, ETC 6/13
2013-7609	09/24/2013	FDA/OGROP/ORA/PA-FO/SAN-	KEN REID	LUMIQUICK DIAGNOSTICS INC, SANTA CLARA, CA - 483, CO

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	10/23/2013	DO/SAN-CB/	WASHINGTON INFORMATION SOURCE	RSP, WARNING LTR, ETC 11/12 TO 12/12
2013-7610	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ZEPPESSIS REPROCESSING LLC, GARDEN CITY, ID - 483, CO RESP, WARNING LTR, ETC 4/13
2013-7611	09/24/2013 10/23/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PETER SCHIFF ENTERPRISES, COOKEVILLE, TN - 483, CO RESP, WARNING LTR, ETC 3/13 TO 4/13
2013-7612	09/24/2013 10/23/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AMRESO, SOLON, OH - EIR, RESP, CORR 10/12 TO 12/12
2013-7613	09/24/2013 10/23/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AIONEX, GOODLETTSVILLE, TN - EIR, RESP, CORR 11/12
2013-7614	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	RIVERPOINT MEDICAL, PORTLAND, OR - EIR, RESP, CORR 1/13 TO 2/13
2013-7615	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	K S CHOI CORP, LOS ANGELES, CA - EIR, RESP, CORR 12/12 TO 2/13
2013-7616	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	FINEMOST CORP, CERRITOS, CA - EIR, RESP, CORR 9/12
2013-7617	09/24/2013 10/23/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	GYRUS ACMI, STAMFORD, CT - EIR, RESP, CORR 7/12 TO 8/12
2013-7618	09/24/2013 10/23/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION SOURCE	GLUTATHIONE CORP, ELMSFORD, NY - EIR, RESP, CORR 9/12 TO 10/12
2013-7619	09/24/2013 10/23/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALEXION PHARMS, CHESHIRE, CT - EIR, RESP, CORR 7/12 TO 8/12
2013-7620	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MICHAEL RING MD, SPOKANE, WA - EIR, RESP, CORR 7/12 TO 8/12
2013-7621	09/24/2013 10/23/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION	PARKS MEDICAL ELECTRONIC, ALOHA, OR - 483, CO RESP, WARNING LTR, ETC 7/12 TO 8/12

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			SOURCE	
2013-7622	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	KEN RIED WASHINGTON INFORMATION SOURCE	LIFEWATCH SERVICES, ROSEMEONT, IL - 483, CO RESP, WARNING LTR, ETC 8/12 TO 9/12
2013-7623	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SEADO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BACTERIN INTERNATIONAL, BELGRADE, MT - 483, CO RESP, WARNING LTR, ETC 7/12
2013-7624	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ABBEY COLOR, PHILADELPHIA, PA - 483, CO RESP, WARNING LTR, ETC 3/12
2013-7625	09/24/2013 10/23/2013	FDA/OGROP/ORASW-FO/DALDO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SOVEREIGN PHARM, FORT WORTH, TX - 483, CO RESP, WARNING LTR, ETC 1/12 TO 2/12
2013-7626	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/ FDA/OMPT/CBER/OCOD/DDOM/ALFB/	KEN RIED WASHINGTON INFORMATION SOURCE	JANET K TILLISCH MD, FARGO, ND - 483, CO RESP, WARNING LTR, ETC 4/13
2013-7627	09/24/2013 10/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	WOCKHARDT LTD, AURANGABAD, INDIA - 483, CO RESP, WARNING LTR, ETC 3/13
2013-7628	09/24/2013 10/23/2013	FDA/OGROP/ORAPA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INTUITIVE SURGICAL INC, SUNNYVALE, CA - 483, CO RESP, WARNING LTR, ETC 4/13 TO 5/13
2013-7629	09/24/2013 10/23/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STEWART COMPUNDING PHARMACY, FAYETTEVILLE, NC - 483, CO RESP, WARNING LTR, ETC 3/13
2013-7630	09/24/2013 10/23/2013	FDA/OGROP/ORACE-FO/PHIDO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ANSAR GROUP, PHILADELPHIA, PA - 483, CO RESP, WARNING LTR, ETC 5/12 TO 6/12
2013-7631	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	DAVID E OUTWATER ESQ OUTWATER & PINCKES LLP	APOGEE - POLYETHYLENE AND PET BOTTLES AND CONTAINERS INVESTIGATIONS, TESTING, LAB RPTS, ETC
2013-7632	09/24/2013 10/23/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	SHERRY L CONDIE X-GEN PHARMACEUTICALS INC	INDOCO REMEDIES LTD, GOA, INDIA - DRUG PROD DOSAGE FORMS, INSPECTIONAL STATUS, INSPS LAST 3 YRS

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2013-7633	09/24/2013 10/23/2013	OC/OCC/	Lytle, Robert	LAWS, RULES, REGULATIONS ETC WHICH FDA USES TO SUPPORT THE CLAIM THAT THE FDA DOES NOT RECOGNIZE PRIVATE MEMBERSHIP ASSOCIATIONS
2013-7634	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	STUTE, HANK	PARAGON VISION SCIENCES - CPT1200119
2013-7635	09/24/2013 10/23/2013	FDA/OC/OES/DFOI/	A SMYTH IOVATE HEALTH SCIENCES INTERNATIONAL INC	CAERS 167755, 165500, 165504
2013-7636	09/24/2013 10/23/2013	FDA/OO/OFBA/OAGS/	TARASUK, JOHN	ROBERT WOTKOWSKI, KEYSTONE PROPERTY RESOURCES INC; MAURICE ELECTRIC - CONTRACT RECS
2013-7637	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRISTIN DAVENPORT GOODWIN PROCTER LLP	PARKER HANNIFIN CORP - INDEGO EXOSKELETON RECS
2013-7638	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	CARLO CASULO MD ASCEND CAPITAL LLC	INSULET CORP - OMNIPOD MDRS 1/13 TO PRESENT
2013-7639	09/24/2013 10/23/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	MARTI GROS ACTITECH	INNOVATIVE FLEXPAC, SPRINGVILLE, UT - REGISTRATION TYPE, STATUS, AUDIT RPTS
2013-7640	09/24/2013 10/23/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMIE YIEH ABBOTT POINT OF CARE INC	TAS PT ONE TEST CARD K955843; COAG-1 PT TEST CARD K882456; COAG-1 PT-NC TEST CARD K904325, ETC
2013-7641	09/24/2013 10/23/2013	CVM/OCD/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JILLIAN NASH ALLTECH INC	DIAMOND V, CEDAR RAPIDS, IA - CORR 7/13 TO 8/13
2013-7642	09/24/2013 10/23/2013	CVM/OCD/ FDA/OGROP/ORASW-FO/KAN-DO/KAN-CB/	JILLIAN NASH ALLTECH INC	PURINA ANIMAL NUTRITION LLC, ST LOUIS, MO - 483S, CORR LAST TEN YRS
2013-7643	09/24/2013 10/23/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JANIS SWABY REXAM HEALTHCARE	REXAM - ACKNOWLEDGEMENT LTRS FOR TYPE III DMFS
2013-7644	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Tomas Friend KIPA AB	PMA P000039
2013-7645	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Karl Gallegos, MD Karl Gallegos	MINOCYCLINE - FAERS
2013-7646	09/25/2013	FDA/OMPT/CDER/GRP/DIDP/	Curtis Hogue	REGADENOSCAN - FAERS

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	10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	DISCOVERY CAPITAL MANAGEMENT	
2013-7647	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Kelli Dryer STRYKER SUSTAINABILITY SOLUTIONS	K101797
2013-7648	09/25/2013 10/24/2013	FDA/OF/CFSAN/OCD/EOS/	Janet Blaschke ICRS, LLC	PAFA DATABASED DATA 09/01/1980 - 08/30/2013
2013-7649	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Dr. Coco Chen Chen, Coco	BRILACIDIN - PHASE 1 AND PHASE 2 CLINICAL STUDY RESULTS
2013-7650	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	Alex Greene Bionova Medical	K060046
2013-7651	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	I Friedman N/A	INTERMUNE - AERS
2013-7652	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Chandrika Vira FITZPATRICK CELLA HARPER & SCINTO	K971819
2013-7653	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Willene Brondum Insys Therapeutics, Inc.	NDA 204242 - SBA
2013-7654	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Irina Rivkind CANTOR FITZGERALD	LINZESS - FAERS
2013-7655	09/25/2013	FDA/OMPT/CDER/GRP/DIDP/	FDA form 483 for USV Limited India	USV LIMITED, INDIA - 483 01/01/2013 - 09/24/2013

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	10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Drug Regulations	
2013-7656	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K100831
2013-7657	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K112394
2013-7658	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Karen Denny TECHLAB, Inc.	K023599
2013-7659	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/OSMP/OOPD/	John Callahan Hapten Pharmaceuticals, LLC	CEPTARIS - APPROVAL RECS 01/01/2004 - 09/01/2013
2013-7660	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elana Markovitz Orthospace Ltd	K121216
2013-7661	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/ ORA/ ORA/	Aram Sethian Quad Capital	ICU MEDICAL, INC - CONSUMER COMPLAINTS 01/01/2007 - 09/24/2013
2013-7662	09/25/2013 10/24/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	Thomas Evans Soltec ventures	ALDRICH CHEMICAL CO - IMPORT RECS FOR SEA SNAIL
2013-7663	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Kelly A. Blessing-Maire Blessing-Maire, Kelly A	VICTOZA - AERS
2013-7664	09/25/2013 10/24/2013	FDA/OC/OES/DFOI/	Shuo Yang UNIVERSITY OF BRITISH COLUMBIA	FOIA REQUEST LOG 01/01/2004 - 08/31/2013
2013-7665	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Coco Chen Chen, Coco	KEVETRIN - PHAES I CLINICAL TRIALS, ADVERSE EVENTS

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2013-7666	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Nathaniel August Mangrove Partners	TAKEDA - CORR WITH FDA RE OMONTYS, PEGINESATIDE
2013-7667	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/ FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/ FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	Ketaki Gokhale BLOOMBERG NEWS	SUN PHARMACEUTICAL INDUSTRIES LTD, CARACO PHARMACEUTICAL LABORATORIES (09/23/2011 - 09/24/2013)
2013-7668	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Joshua Clark Davis DUKE UNIVERSITY	OHSAWA FOUNDATION, NY, NY - INSPECTION RECS 01/01/1960 - 01/01/1970
2013-7669	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	Joshua Clark Davis DUKE UNIVERSITY	NEW AGE NATURAL FOODS STORE, SAN FRANCISCO, CA - INSPECTION RECS 01/01/1964 - 12/31/1973
2013-7670	09/25/2013 10/24/2013	FDA/OF/CFSAN/OCD/EOS/	Thomas Mullarkey MORNINGSTAR COSULTING INC	MONSTER ENERGY DRINKS - AERS
2013-7671	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	LORILLARD TOBACCO, DANVILLE, VA - INSPECTOR DIARIES
2013-7672	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Denise Bennington Ascension Technology Corporation	ASCENSION TECHNOLOGY CORPORATION, SHELBURNE, VT - INVESTIGATION STATUS
2013-7673	09/25/2013 10/24/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Thomas Leusner Prirista	SHIRE, LEXINGTON, MA - BIOLOGICS PRODUCT DEVIATION REPORTS 09/01/2012 - 09/23/2013
2013-7674	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Brian Lemasters Brian Lemasters	INSPIRE-MD - ADVERSE EVENTS, 483 1/01/2010 - 09/22/2013
2013-7675	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John Strelecki STRELECKI, SAMUEL J	IRONWOOD CANCER AND RESEARCH CENTER, DR MIKHAIL SHTIVELBAND 03/01/2012 - 12/31/2012

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2013-7676	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Joy V. Rousso Shapiro Capital Management	MALLINKRODT PHARMACEUTICALS MNK-395 - NDA
2013-7677	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	CJ Sylvester Catapult. Ltd.	JETREA - AERS
2013-7678	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	Joshua Clark Davis DUKE UNIVERSITY	EREWON TRADING CO - INSPECTION RECS 01/01/1966 - 12/31/1973
2013-7679	09/25/2013 10/24/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Tommy Noh Wilson Sonsini Goodrich & Rosati, P.C.	MECHLORETHAMINE HYDROCHLORIDE - APPROVAL HISTORY
2013-7680	09/25/2013 10/24/2013	FDA/OC/OES/DFOI/	Stace Sirmans UNIVERSITY OF FLORIDA	FOIA REQUEST LOG 01/01/2008 - 08/01/2013
2013-7681	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Timothy B Bassett Pura Vida Investments	JUXTAPED, KYNAMRO - AERS
2013-7682	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SNUFF - EXHIBITS 10/3/2011
2013-7683	09/25/2013 10/24/2013	FDA/OF/CFSAN/OCD/EOS/ ORA/ ORA/	HEATHER GALE OLSSON FRANK WEEDA TERMAN MATZ PC	CADMIUM IN CHOCOLATE - SAFETY ASSESSMENT MEMO & RPT 9/18/13
2013-7684	09/25/2013 10/24/2013	FDA/OMPT/CTP/OD/ OC/OEXA/OPA/	CAROLLO, RUSSELL	SERVICES, COUNSEL, ADVICE PROVIDED BY GOOGLE - CORR, FOIA REQUESTS, TRAVEL RECS, ETC
2013-7685	09/25/2013 10/24/2013	FDA/OC/OES/DFOI/	PRICE, GRETA S	INDIVIDUAL RECS
2013-7686	09/25/2013 10/24/2013	FDA/OF/CFSAN/OCD/EOS/	CARRIE TEETER Keller and Heckman LLP	NIPPON STEEL & SUMITOMO METAL CORP - FCN 1253
2013-7687	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MIKE SHEPARD RENE MEDICAL	FLOWMEDICA INC - BENEPHIT BIFURCATED INFUSION CATHETER, BENEPHIT 5FR INTRODUCER SHEATH SYS K050205
2013-7688	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	MIKE SHEPARD RENE MEDICAL	FLOWMEDICA INC - BENEPHIT INFUSION SYS K082163

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2013-7689	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CADRIOPULMONARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR K112360 RECS 1/11 TO 12/11
2013-7690	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CARDIOPULMONARY AG, MAQUET CARDIOVASCULAR LLC - EIRS. 483S. WARNING LTRS, ETC
2013-7691	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/NWJ- DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CARDIOPULMOMARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR RECALL RECS,CORR, RVWS, ETC
2013-7692	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMES MAGUIRE DAVID ROSEN & ASSOCIATES PC	MAQUET CARDIOPULMONARY AG - QUADROX ID DIFFUSION MEMBRANE OXYGENATOR K101153
2013-7693	09/25/2013 10/24/2013	FDA/OF/CFSAN/OCD/EOS/	MICHELLE L BRISCOE BROOKS RAND LABS	RICE DATA EXCEL FORMAT
2013-7694	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	HILL, MELISSA D	INDIVIDUAL RECS
2013-7695	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	OLYMPIA WOMENS HEALTH, OLYMPIA, WA - EIR, CO RESP 2/13 TO 3/13
2013-7696	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/ATL- DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - EIRS, RESP, CORR 1/12 TO 3/12
2013-7697	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/DAL- DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CELLTEX THERAPEUTICS, SUGARLAND, TX - EIRS, RESP, CORR 4/12
2013-7698	09/25/2013 10/24/2013	FDA/OGROP/ORAPA-FO/SEA- DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PUGET SOUND BLOOD CENTER, SEATTLE, WA - 1/13 TO 2/13
2013-7699	09/25/2013 10/24/2013	FDA/OGROP/ORASW-FO/DEN- DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	WESTONE LABORATORIES, COLORADO SPRINGS, CO - EIR, CO RESP 7/12
2013-7700	09/25/2013 10/24/2013	FDA/OGROP/ORASE-FO/FLA- DO/FLA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	NEXERA MEDICAL, FORT LAUDERDALE, FL - EIR, CO RESP 7/12
2013-7701	09/25/2013 10/24/2013	FDA/OGROP/ORACE-FO/MIN- DO/MIN-CB/	KEN REID WASHINGTON INFORMATION	COCOKEFIR LLC, MEDINA, MN - EIR, CO RESP 5/12

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			SOURCE	
2013-7702	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	TISSUE BANK INT'L, MEMPHIS, TN - 483, CO RESP, WARNING LTR 6/12
2013-7703	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - EIRS, RESP, CORR 2/12 TO 3/12
2013-7704	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MIR-COM PRODUCTS, CENTRAL CITY, PA - EIR, RESP, CORR 6/12
2013-7705	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MARTIN S BALIN MD, CHICAGO, IL - EIR, RESP, CORR 6/12 TO 8/12
2013-7706	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	COCOKEFIR LLC, MEDINA, MN - 483, CO RESP, WARNING LTR 5/12
2013-7707	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	NEXERA MEDICAL, FORT LAUDERDALE, FL - 483, CO RESP, WARNING LTR 7/12
2013-7708	09/25/2013 10/24/2013	FDA/OGROP/ORA/SW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	WESTONE LABORATORIES, COLORADO SPRINGS, CO - 483, CO RESP, WARNING LTR 7/12
2013-7709	09/25/2013 10/24/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PERFORMANCE PRODUCTS, ST LOUIS, MO - 483, CO RESP, WARNING LTR 7/12
2013-7710	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MARTIN A BALIN MD, CHICAGO, IL - 483, CO RESP, WARNING LTR 6/12 TO 8/12
2013-7711	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	GYRUS ACMI, STAMFORD, CT - 483, CO RESP, WARNING LTR 7/12 TO 8/12
2013-7712	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STATRX USA, GAINESVILLE, GA - 483, CO RESP, WARNING LTR 2/12
2013-7713	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	I SHAY COSMETICS, GARDEN, CA - 483, CO RESP, WARNING LTR 2/12

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2013-7714	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOCOMPATIBLES INC, OXFORD, CT - EIR, CO RESP 2/13 TO 4/13
2013-7715	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AGNESIAN HEALTHCARE, FOND DU LAC, WI - EIR, CO RESP 11/12
2013-7716	09/25/2013 10/24/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Makoto Kaino Japan Asia Clinical Research Product Creation Unit, Eisai Co., Ltd	CLINICAL INVESTIGATORS - 483 (01/01/2008 - 09/25/2013)
2013-7717	09/25/2013 10/24/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	brandi kopp Brandi Kopp	JUICE PLUS COMPLETE - TEST RESULTS (06/24/2013 - 09/24/2013)
2013-7718	09/25/2013 10/24/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MEGA SUN INC, ST LOUIS, MO - EIR, CO RESP 2/12 TO 3/12
2013-7719	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	Sara Neily The Doyle Firm	STRYKER TRIDENT HIP SYSTEM - RECALL RECS, WARNING LETTER (01/01/2006 - 09/24/2013)
2013-7720	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	Rachel Johnson FOI Services, Inc.	AMERICAN SNUFF, WINSTON-SALEM, NC - INVESTIGATOR DIARIES
2013-7721	09/25/2013 10/24/2013	FDA/OC/OES/ FDA/OMPT/CTP/OD/	Rachel Johnson FOI Services, Inc.	E CIGARETTE REGULATIONS - CORR
2013-7722	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	Rachel Johnson FOI Services, Inc.	LORRILARD TOBACCO, DANVILLE, VA - EXHIBITS FOR 7/26/2012 INSPECTION
2013-7723	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Elyse Ball University of Akron Research Foundation	P960052
2013-7724	09/25/2013 10/24/2013	CVM/OCD/	Sandy O'Kelley Merial Limited	MERIAL LIMITED - RECS RE G-002819-G-0002-AD, G-002893-G-0002-AD, G-002819 G-002893
2013-7725	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACCLARENT, MENLO PARK, CA - EIR, CO RESP 1/13 TO 2/13
2013-7726	09/25/2013	FDA/OGROP/ORA/SW-FO/KAN-DO/KAN-CB/	KEN REID	PERFORMANCE PRODUCTS, ST LOUIS, MO - EIR, RESP,CORR 7/12

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	10/24/2013		WASHINGTON INFORMATION SOURCE	
2013-7727	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	VALLEY HEALTH WINCHESTER MEDICAL CTR IRB, WINCHESTER, VA - EIR, CO RESP 1/13 TO 2/13
2013-7728	09/25/2013 10/24/2013	FDA/OMPT/CDRH/OCER/DFOI/	Zeeshan Raza Raza, Zeeshan	HEPAHOPE - CLINICAL HOLD RECS 01/01/2000 - 09/24/2013
2013-7729	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STATRX USA, GAINESVILLE, GA - EIR, RESP, CORR 2/12
2013-7730	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - 483, CO RESP, WARNING LTR 11/11 TO 12/11
2013-7731	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	COMAPNY INTUITIVE SURGICAL INC, SUNNYVALE, CA - EIR, RESP, CORR 4/13 TO 5/13
2013-7732	09/25/2013 10/24/2013	FDA/OGROP/ORA/NE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SPINE FRONTER, BEVERLY, MA - 483, CO RESP, WARNING LTR 5/12 TO 7/12
2013-7733	09/25/2013 10/24/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	I SHAY COSMETICS, GARDENA, CA - EIR, RESP, CORR 2/12
2013-7734	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LAKEWOOD LLC, LAKEWOOD, NJ - 483, CO RESP, WARNING LTR 2/12 TO 3/12
2013-7735	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SCM TRUE AIR TECHNOLOGIES, LOUISVILLE, KY - EIR, RESP, CORR 5/13
2013-7736	09/25/2013 10/24/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	MIR COM PRODUCTS, CENTRAL CITY, PA - 483, CO RESP, WARNING LTR 6/12
2013-7737	09/25/2013 10/24/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CELL TEX THERAPEUTICS, SUGARLAND, TX - 483, CO RESP, WARNING LTR 4/12
2013-7738	09/25/2013 10/24/2013	FDA/OGROP/ORA/SE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMERIEUX, DURHAM, NC - 483, CO RESP, WARNING LTR 1/12 TO 3/12

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2013-7739	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheila Gray WKEF/WRGT TV	MIRENA IUD - AERS
2013-7740	09/26/2013 10/25/2013	CVM/OCD/	Becky Armfield NOVARTIS ANIMAL HEALTH US INC	NADA 141-406 FOIA SUMMARY
2013-7741	09/26/2013 10/25/2013	FDA/OGROP/ORA/SE-FO/NOL- DO/NOL-CB/	Franco Medeiros PROCTER & GAMBLE	GLAXOSMITHKLINE, MEMPHIS, TN - INSPECTION RECS 09/01/1990 - 09/25/2013
2013-7742	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Sheena M. Posey Norris The National Academies (Institute of Medicine)	NDA 050786 - ACTION LETTER
2013-7743	09/26/2013 10/25/2013	FDA/OC/OES/DFOI/	Kari Twaite BEVERIDGE & DIAMOND PC	FOIA REQUESTS FILED WITH CFSAN 08/01/2012 - 09/25/2013
2013-7744	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Brooke Hazan KENYON & KENYON LLP	IND 21487 - CLINICAL STUDY
2013-7745	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Intertox< Inc. Intertox, Inc.	K914776
2013-7746	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Manish Ahuja BioTex Inc.	K944463
2013-7747	09/26/2013 10/25/2013	FDA/OGROP/ORA/CE-FO/MIN- DO/MIN-CB/	b. burgess BURGESS, BERNIE	EI ENDORSEMENT FOR FEI 3004927371
2013-7748	09/26/2013 10/25/2013	FDA/OF/CFSAN/OCD/EOS/	Lauren Farruggia Hyman, Phelps & McNamara P.C.	ZARBEE - COMMUNICATIONS WITH FDA RE LABEL CLAIMS
2013-7749	09/26/2013 10/25/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 1041
2013-7750	09/26/2013 10/25/2013	FDA/OF/CFSAN/OCD/EOS/	Rachel Johnson FOI Services, Inc.	FAP 1041
2013-7751	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Rachel Johnson FOI Services, Inc.	NDA 18680 - FINAL LABELING AND PATIENT INSERT; NDA 18680 S 60- MATERIALS SENT OR RECEIVED BY FDA

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		FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/		
2013-7752	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	ESSURE - ADVERSE EVENTS
2013-7753	09/26/2013 10/25/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	DIANNE L CHAMBERS HOGAN LOVELLS US LLP	C PACIFIC FOODS - CANNED MUSHROOM SLICED 6 CANS RECALL F-17590-2013 ANALYTICAL RECS, TEST RESULTS
2013-7754	09/26/2013 10/25/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/SAN- DO/SAN-CB/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	CROWN PACIFIC INTERNATIONAL LLC - HAWAII FRESH SWEET BASIL F-1873-2013 ANALYTICAL RECS, TEST RESULTS
2013-7755	09/26/2013 10/25/2013	ORA/ ORA/ FDA/OGROP/ORA/PA-FO/LOS- DO/LOS-CB/	DIANNE L CHAMBERS HOGAN LOVELLS LLP	BAO GONG DA INC - AMERICAN GINSENG F-153-2013 ANALYTICAL RECS, TEST RESULTS
2013-7756	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	KEVIN E MINNICH B BRAUN MEDICAL INC	B BRAUN MEDICAL INC - INFUSOMAT SPACE PUMP INFUSION SYS SOFTWARE J K103572; PERFUSOR SPACE SYRINGE PUMP SOFTWARE J K122452 REVIEWER'S NOTES
2013-7757	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	ERIC D FADER DAY PITNEY LLP	ADVVERSE EVENT KEYS 3053543, 3906483, 2531355
2013-7758	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/	JAMIE YIEH ABBOTT POINT OF CARE INC	OPTIC MEDICAL SYSTEMS - K131126
2013-7759	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	SHEA N SHAVER REILLY POZNER LLP	EFFEXOR (VENLAFAXINE HCL) NDA 20-151 - CORR, APRVL LTRS, AERS, ETC
2013-7760	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JODY L GREEN DENVER HEALTH ROCKY MOUNTAIN POISON & DRUG CENTER	ISR 7382479, 7814351, 8067430, ETC - COUGH & COLD PREPARATIONS
2013-7761	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	S ALBERT EDWARDS S ALBERT EDWARDS, PHARM D	PRESCRIPTION DRUG WRAP -UP (DESI-2) - RONDEX, CARBAXAFED LTR

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2013-7762	09/26/2013 10/25/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JOHN CREWDSON PROJECT ON GOVERNMENT OVERSIGHT	PRADAXA - AERS 12/31/12 TO PRESENT
2013-7763	09/26/2013 10/25/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	FRIEDMAN, ROBERT	BUCCASTEM 3MG TABS - AERS 1969 TO PRESENT
2013-7764	09/26/2013 10/25/2013	FDA/OGROP/ORA/CE-FO/NWJ- DO/NWJ-CB/	KIM C CAPONE PORZIO LIFE SCIENCES	CARACO PHARMACEUTICAL LABORATORIES LTD, CRANBURY, NJ - EIRS, 483S 6/28/11
2013-7765	09/26/2013 10/25/2013	FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/ ORA/ ORA/	SAK, DAN	BACK CENTER, MELBOURNE, FL - MULTI-DOSE CONTAINER OF MPA PICTURE
2013-7766	09/26/2013 10/25/2013	FDA/OF/CFSAN/OCD/EOS/	WILBUR JOHNSON JR COSMETIC INGREDIENT REVIEW	PENTAERYTHRYL TETRA-DL-T-BUTYL HYDROXYHYDROCINAMATE - CHEMICAL & PHYSICAL PROPERTIES, METABOLISM BIOAVL, DERMAL PENETRATION, ETC
2013-7767	09/26/2013 10/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/SE-FO/FLA- DO/FLA-CB/	PAUL T LANDIS FAIN ANDERSON VANDERHOEF PLLC	KINGPIN TATTOO INC - ONE TATTO INK RECALL F-2112- 2012 RPTS, FINAL CONCLUSIONS
2013-7768	09/26/2013 10/25/2013	FDA/OF/CFSAN/OCD/EOS/ FDA/OGROP/ORA/PA-FO/SEA- DO/SEA-CB/	JACQUELINE J CHAN K&L GATES	METAGENIC INC, GIG HARBOR, WA - WARNING LTR SEA 13-27 CORR, NOTES, DOCUMENTATION, ETC 8/12/13
2013-7769	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Michelle Garcia Garcia, Michelle	ESSURE - FIVE YEAR POST APPROVAL STUDY
2013-7770	09/27/2013 10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	b. burgess BURGESS, BERNIE	COMPLAINTS FILED IN CDER DATABASE AFTER 1639
2013-7771	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Luis Rolfo Luis Rolfo	CUTOFF LEVELS FOR PSYCHEMEDICS MARIJUANA HAIR DRUG TEST
2013-7772	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Peter Mattesson Hotswaqp Stockholm AB	K881183

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2013-7773	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Byron J Wyche Capstone Investment Advisors	NUMBER OF FACILITIES APPROVED FOR DIGITAL MAMMOGRAPHY SCREENING BY YEAR; NUMBER OF DIGITAL MAMMOGRAPHY MACHINES APPROVED FOR SERVICE BY YEAR; NUMBER OF FACILITIES APPROVED FOR TOMOSYNTHESIS 3D DIGITAL MAMMOGRAPHY BY YEAR ETC
2013-7774	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/	Joel Bamford Cochrane Skin Group	ADVERSE EVENT SUMMARIES - VARIOUS DRUGS
2013-7775	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Amanda Dykeman N/A	ESSURE - FIVE YEAR POST STUDY
2013-7776	09/27/2013 10/28/2013	FDA/OMPT/OSMP/OOPD/	Joshua A. Malamud Hyman, Phelps & McNamara P.C.	NYMALIZE - ORPHAN DRUG DESIGNATION
2013-7777	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	NSQ1 Integrated Plasmonics	K914469, K913105, K990688 ETC
2013-7778	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101200
2013-7779	09/27/2013 10/28/2013	CVM/OCD/	PJ Huffstutter Thomson Reuters/Reuters News	ZILPATEROL - AERS
2013-7780	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K101250
2013-7781	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103025
2013-7782	09/27/2013 10/28/2013	FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CDER/ERP/DIDP/ FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Nicholas Croce none	IND 15376
2013-7783	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K103088
2013-7784	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Rachel Johnson FOI Services, Inc.	K123864
2013-7785	09/27/2013	FDA/OMPT/CDER/ERP/DIDP/	Heidi Fezatte	Oxylone Topical fluorometholone NDA

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	10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Elorac Inc.	
2013-7786	09/27/2013 10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Edward Zane Chilton Investment Company	QSYMIA - AERS
2013-7787	09/27/2013 10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	jeffrey gardner Jeffrey Gardner	IPI-145 - AERS
2013-7788	09/27/2013 10/28/2013	FDA/OMPT/CDRH/OCER/DFOI/	Joshua Jennings COWEN AND COMPANY	P950022/S042
2013-7789	09/27/2013 10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	jeffrey gardner Jeffrey Gardner	PRO044, PRO045, PRO053 - AERS
2013-7790	09/27/2013 10/28/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/ FDA/OMPT/CTP/OD/	Dan Lieberman ABC NEWS	VAPOR SHARK, VAPOR HOG; E-CIGARETTE - COMPLAINTS 09/01/2013 - 09/26/2013
2013-7791	09/27/2013 10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ ORA/ ORA/	Thomas Althausen Eccleston and Wolf, PC	NECC - METHYLPREDNISOLONE ACETATE 80 Mg/ml Lot 05212012@68
2013-7792	09/27/2013 10/28/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	Angelia Slayton INC RESEARCH CONSULTING & SUBMISSIONS	NYCOMED, SINGEN, GERMANY - EIR 6/2/09
2013-7793	09/27/2013 10/28/2013	FDA/OGROP/ORA/CE-FO/PHI-DO/PHI-CB/	Rebekah Cafrelli Rebekah Cafrelli	HERSHEY MEDICAL CENTER BLOOD BANK - REPORTS SUBMITTED TO FDA 07/11/2013 - 08/15/2013
2013-7794	09/27/2013	FDA/OMPT/CDRH/OCER/DFOI/	Angela Lynch	STOP/ESSURE - TRIAL RECS

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	10/28/2013		Angela Lynch	
2013-7795	09/30/2013 10/29/2013	FDA/OGROP/ORA/PA-FO/LOS-DO/LOS-CB/	John H. Reed Reed, John H	ROYAL RAYMOND FIFE, SAN DIEGO, CA - INVESTIGATION RECS 01/01/1910 - 12/31/2012
2013-7796	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	Isabella Biedenharn Isabella Biedenharn	YASMIN - AERS
2013-7797	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Dora Fong KARL STORZ ENDOSCOPY AMERICA INC	K124031
2013-7798	09/30/2013 10/29/2013	FDA/OC/OES/DDM/	Sarah L. Scott Goodell DeVries Leech & Dann LLP	FDA COMMITTEE MEETING FOR PEDIATRIC IBUPROFEN - MEETING MINUTES 01/01/1994 - 06/20/1995
2013-7799	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBEMARLE CORPORATION, SOUTH HAVEN, MI - EIR SUMMARY (01/01/2012 - 01/31/2012)
2013-7800	09/30/2013 10/29/2013	FDA/OC/OES/DDM/	Sarah L. Scott Goodell DeVries Leech & Dann LLP	FDA OTC DRUG ADVISORY COMMITTEE - MTG MINUTES WITH DR ERIC PAUL BASS 01/01/1990 - 12/31/1996
2013-7801	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	Rachelle Lyon Janus Capital Group Attn: Rachelle Lyon	SENSIENT TECHNOLOGIES CORP - 483, RESPONSE 09/01/2011 - 09/27/2013
2013-7802	09/30/2013 10/29/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	Curtis Walcker VRP Manufacturing, LLC	METAGENICS - RESPONSE TO WARNING LETTERS
2013-7803	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Heather Neely Neely, Heather	K131345
2013-7804	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBERMARLE CORPORATION, SOUTH HAVEN, MI - EIR SUMMARY 02/12/2013 - 02/15/2013
2013-7805	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBEMARLE CORPORATION, SOUTH HAVEN, MI - EIR 02/12/2013 - 02/15/2013
2013-7806	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	Rebecca Dandeker MORGAN, LEWIS & BOCKIUS	ALBERMARLE CORPORATION, SOUTH HAVEN, MI - EIR 01/01/2012 - 01/31/2012
2013-7807	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	Mary E. Lynn The Windward Company	WIL RESEARCH LABORATORIES, ASHLAND, OH - EIR 03/06/2013 - 03/21/2013
2013-7808	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OGROP/ORA/NE-FO/NYK-	Soma Das The Economic Times, The Times of India	OHM LABS, US - 483 06/29/2012 - 09/01/2013

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		DO/NYK-DCB/		
2013-7809	09/30/2013 10/29/2013	ORA/OCI/ ORA/OCI/ FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	Doe J	INDIVIDUAL RECS
2013-7810	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randall Taradash Taradash Law Office	HOSPIRA PLUMB PUMP - MAUDE REPORTS 09/28/2004 - 09/28/2013
2013-7811	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	Randall Taradash Taradash Law Office	ABBOTT PLUMB PUMP - MAUDE REPORTS 10/28/2004 - 09/28/2013
2013-7812	09/30/2013 10/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ALFB/	Matthew Hodgson Matthew Hodgson	C FORDHAM VON REYN, MD - WARNING LETTER FOLLOW UP
2013-7813	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	JANET K TILISCH MD, FARGO, ND - EIR, CO RESP, CORR 4/13
2013-7814	09/30/2013 10/29/2013	FDA/OGROP/ORA/SE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PETER SCHIFFENT ENTERPRISES, COOKEVILLE, TN - EIR, CO RESP, CORR 3/13 TO 4/113
2013-7815	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/ FDA/OGROP/ORA/PA-FO/SAN-DO/SAN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LUMIQUICK DIAGNOSTICS INC, SANTA CLARA, CA - EIR, CO RESP, CORR 11/12 TO 12/12
2013-7816	09/30/2013 10/29/2013	FDA/OGROP/ORA/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ZEPPESSIS REPROCESSING LLC, GARDEN CITY, ID - EIR, CO RESP, CORR 4/13
2013-7817	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	AUTOMATED OPHTHALMIC, COLUMBIA, MD - EIR, CO RESP, CORR 2/13 TO 3/13
2013-7818	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/DET-DO/DET-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BIOMEDIX INC, BLOOMINGTON, IN - EIR, CO RESP, CORR 2/13 TO 3/13
2013-7819	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ACELL INC, COLUMBIA, MD - EIR, CO RESP, CORR 11/12 TO 12/12
2013-7820	09/30/2013 10/29/2013	FDA/OGROP/ORA/SW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC, MINERAL WELLS, TX - EIR, CO RESP, CORR 1/13 TO 2/13

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2013-7821	09/30/2013 10/29/2013	FDA/OGROP/ORASW-FO/DAL-DO/DAL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SOVEREIGN PHARMS, FORT WORTH, TX - EIR, CO RESP, CORR 1/12 TO 2/12
2013-7822	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/NWJ-DO/NWJ-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CISPHARMA, CRANBURY, NJ - EIR, CO RESP CORR 3/12 TO 4/12
2013-7823	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NYK-DO/NYK-DCB/	KEN REID WASHINGTON INFORMATION SOURCE	TRANSONIC SYSTEMS INC, ITHACA, NY - EIR, CO RESP, CORR 2/13 TO 3/13
2013-7824	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CONAIR CORP, STAMFORD, CT - EIR, CO RESP, CORR 5/13
2013-7825	09/30/2013 10/29/2013	FDA/OGROP/ORANE-FO/NWE-DO/NWE-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SPINE FRONTIER, BEVERLY, MA - EIR, CO RESP, CORR 5/12 TO 7/12
2013-7826	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/ATL-DO/ATL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	STEWART COMPOUNDING PHARMACY, FAYETTEVILLE, NC - EIR, CO RESP, CORR 3/13
2013-7827	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	HAIR LABS INC, NASHVILLE, TN - EIR, CO RESP, CORR 4/13
2013-7828	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CIN-DO/CIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	SCM TRUE AIR TECHNOLOGIES, LOUISVILLE, KY - 483, CO RESP, WARNING LTR, ETC 5/13
2013-7829	09/30/2013 10/29/2013	FDA/OGROP/ORAPA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	BACTERIN INTERNATONAL, BELGRADE, MT - EIR, CO RESP, CORR 7/12
2013-7830	09/30/2013 10/29/2013	FDA/OGROP/ORASE-FO/NOL-DO/NOL-CB/	KEN REID WASHINGTON INFORMATION SOURCE	TISSUE BANK INTERNATIONAL / NATIONAL EYE BANK CENTER, MEMPHIS, TN - EIR, CO RESP, CORR 6/11
2013-7831	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CHI-DO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LIFEWATCH SERVICES, ROSEMONT, IL - EIR, CO RESP, CORR 8/12 TO 9/12
2013-7832	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/PHI-DO/PHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ABBEY COLOR, PHILADELPHIA, PA - EIR, CO RESP, CORR 3/12
2013-7833	09/30/2013	FDA/OGROP/ORACE-FO/PHI-	KEN REID	ANSAR GROUP, PHILADELPHIA, PA - EIR, CO RESP, CORR

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	10/29/2013	DO/PHI-CB/	WASHINGTON INFORMATION SOURCE	5/12 TO 6/12
2013-7834	09/30/2013 10/29/2013	FDA/OGROP/ORAP/PA-FO/SEA-DO/SEA-CB/	KEN REID WASHINGTON INFORMATION SOURCE	PARKS MEDICAL ELECTRONICS, ALOHA, OR - EIR, CO RESP, CORR 7/12 TO 8/12
2013-7835	09/30/2013 10/29/2013	FDA/OGROP/ORASW-FO/DEN-DO/DEN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	EDWARDS LIFESCIENCES, DRAPER, UT - EIR, CO RESP, CORR 1/13 TO 2/13
2013-7836	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/MIN-DO/MIN-CB/	KEN REID WASHINGTON INFORMATION SOURCE	LIFESERVE BLOOD CENTER, DES MOINES, IA - EIR, CO RESP, CORR 6/13
2013-7837	09/30/2013 10/29/2013	FDA/OGROP/ORACE-FO/CHIDO/CHI-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALMA LASERS INC, BUFFALO, GROVE, IL - EIR, CO RESP, CORR 1/13
2013-7838	09/30/2013 10/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	INNOVACYN INC, RIALTO, CA - EIR, CO RESP, CORR 11/11 TO 12/11
2013-7839	09/30/2013 10/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	CUSTOM COMPOUNDING CENTERS, LOS ALAMITOS, CA - EIR, CO RESP, CORR 11/12 TO 12/12
2013-7840	09/30/2013 10/29/2013	FDA/OGROP/ORAP/PA-FO/LOS-DO/LOS-CB/	KEN REID WASHINGTON INFORMATION SOURCE	ALPHA MEDICAL INSTRUMENTS, MISSION VIEJO, CA - EIR, CO RESP, CORR 12/12/ TO 1/13
2013-7841	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	KEN REID WASHINGTON INFORMATION SOURCE	WOCKHARDT LTD, AURANGABAD, INDIA - EIR, CO RESP, CORR 3/13
2013-7842	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUTS INC - CIDEX OPA SOL K002401
2013-7843	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	MINNTECH CORP - RAPICIDE OPA-28 K120306
2013-7844	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	SERIM RESEARCH CORP - RAPICIDE OPA-28 TEST STRIPS K120652
2013-7845	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	SERIM RESEARCH CORP - CIDEX OPA SOL TEST STRIPS K992341
2013-7846	09/30/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS	ADVANCED STERILIZATION PRODUCTS INC - CIDEX OPA

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	10/29/2013	FDA/OC/OES/DFOI/	MEDICAL CHEMICAL CORP	CONCENTRATE K032959
2013-7847	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ALBERT BROWNE LTD - BROWNE CIDEX OPA INDICATOR K991709
2013-7848	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUCTS INC - CIDEX OPA SOL K991487
2013-7849	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/	KRIS J KONTIS MEDICAL CHEMICAL CORP	ADVANCED STERILIZATION PRODUCTS INC - CIDEX OPA SOL K001381
2013-7850	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	TRIDENT - PSL ACETABULAR SHELLS; PSL HA SOLID BACK - PMA, 510K
2013-7851	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	TRIDENT - ACETABULAR SHELLS K001448
2013-7852	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/NWJ-DO/NWJ-CB/ FDA/OMPT/CDRH/OCER/DFOI/	MELISSA A. JONES LAW OFFICES OF RICHARD N SHAPIRO	HOWMEDICA OSTEONICS CORP - ABC/TRIDENT SYSTEMS PMA
2013-7853	09/30/2013 10/29/2013	FDA/OMPT/CDRH/OCER/DFOI/ FDA/OC/OES/DFOI/ FDA/OC/OES/DFOI/	EVA STEINICK HEMOCUE INC	ROCHE - IMFORM; K121679; ABBOT - FREE STYLE PRECISIONS PRO K130094; NOVA - STATATRIIP K063821
2013-7854	09/30/2013 10/29/2013	FDA/OC/OES/DDM/	KRISTIO O SMEDLEY Center for Regulatory Services, Inc.	DKT 1995-S-0039 - 75 DAY NOTICE
2013-7855	09/30/2013 10/29/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONALD N. BLUE ZETETIC	ETHICON - US/NM SUTURE ABSORBABLE & NON ABSORBABLE ENTRY #AV3-0040036-1
2013-7856	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/BLT-DO/BLT-CB/	DONALD N. BLUE ZETETIC	ETHICON - ETHIBOND EXCEL SUTURE ENTRY NO UPS-8151908-7
2013-7857	09/30/2013 10/29/2013	FDA/OGROP/ORA/SE-FO/FLA-DO/FLA-CB/	DONAL N. BLUE ZETETIC	ETHICON - NON ABSORBABLE SUTURES & ABSORBABLE SUTURES ENTRY NO AV3-0039869-0
2013-7858	09/30/2013 10/29/2013	FDA/OGROP/ORA/NE-FO/NYK-DO/NYK-DCB/	K. MICHELLE VASSALLO LINCARE INC	CLARK RESPIRATORY & MEDICAL SUPPLY, HIGHLAND, NY - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-7859	09/30/2013 10/29/2013	FDA/OGROP/ORA/CE-FO/CIN-DO/CIN-CB/	K. MICHELLE VASSALLO LINCARE INC	OXY MED INC, MIDDLETON, OH - 483, EIR, WARNING LTR 1/98 TO PRESENT
2013-7860	09/30/2013 10/29/2013	FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/ FDA/OMPT/CDER/ORP/DIDP/	MICHELE SINOWAY, PhD LACHMAN CONSULTANT SERVICES INC	USV LIMITED, MUMBAI, INDIA - 483 7/6/13

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		FDA/OMPT/CDER/GRP/DIDP/		
2013-7861	09/30/2013 10/29/2013	FDA/OMPT/CBER/OCOD/DDOM/ ALFB/	Jerome Lew Walt Disney Studios	OSTEOGENICS BIOMEDICAL - DATE OF SUBMISSION, FEI
2013-7862	09/30/2013 10/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	COLLEEN M. HEISEY JONES DAY	DR REDDYS LABS - AZACITIDINE ANDA 01-537 APRVL
2013-7863	09/30/2013 10/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	JAYA AYYAGARI DR REDDY'S LABORATORIES INC	SUN PHARMA GLOBAL - DOXORUBICIN HCL (LIPOSOMAL) ANDA 03-263 SBA
2013-7864	09/30/2013 10/29/2013	FDA/OGROP/ORA/SE-FO/SJN- DO/SJN-CB/	MAGGIE IHA-PETERSEN FLEGENHEIMER INTERNATIONAL INC	ENTRY NO MU8-0029278-9
2013-7865	09/30/2013 10/29/2013	FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/ FDA/OMPT/CDER/GRP/DIDP/	NEMEL, RANDY	GABAPENTIN - AER
2013-7866	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 8/26-30/13
2013-7867	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY CLOSED LOG 9/2-6/13
2013-7868	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 8/26-30/13
2013-7869	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LAUREN S. BARR JH BARR & ASSOCIATES LLC	DAILY LOG 9/2-6/13
2013-7870	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY CLOSED LOG 8/26-30/13
2013-7871	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 8/26-30/13
2013-7872	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP CanReg, Inc.	DAILY LOG 9/2-6/13
2013-7873	09/30/2013	FDA/OC/OES/DFOI/	LISA TARRISON-SCHRAMP	DAILY CLOSED LOG 9/2-6/13

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	10/29/2013		CanReg, Inc.	
2013-7874	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 9/2-6/13
2013-7875	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	DAILY LOG 8/26-30/13
2013-7876	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 9/2-6/13
2013-7877	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	BARBARA JONES DOMINION GROUP INC	DAILY LOG 8/26-30/13
2013-7878	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 9/2-6/13
2013-7879	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	GLADYS B. TONKIN Center for Regulatory Services, Inc.	DAILY LOG 8/26-30/13
2013-7880	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 8/26-30/13
2013-7881	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY LOG 9/2-6/13
2013-7882	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 8/26-30/13
2013-7883	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	FOI Services, Inc.	DAILY CLOSED LOG 9/2-6/13
2013-7884	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEBI COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 9/2-6/13
2013-7885	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEBRA L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY LOG 8/26-30/13
2013-7886	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	SANDY FRIEDMAN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 8/26-30/13
2013-7887	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEBI L. COHEN WOLTERS KLUWER LAW & BUSINESS	DAILY CLOSED LOG 9/2-6/13

Disclosure FOI Request Log Date range from 10/01/2012 to 09/30/2013 Report

Total Records: 9990

Control #	Recd Date / Due Date	Action Office	Signature/ Requester	Subject
2013-7888	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 8/26-30/13
2013-7889	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DAVID McFARLAND FDA REVIEW/FDA WEBVIEW	DAILY CLOSED LOG 9/2-6/13
2013-7890	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2013-2471, 3021, 3532
2013-7891	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2013-721, 930, 737
2013-7892	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2013-142, 8434, 8069
2013-7893	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	KENNETH REID WASHINGTON INFORMATION SOURCE	2012-7797, 2191, 2975
2013-7894	09/30/2013 10/29/2013	FDA/OC/OES/DFOI/	DEERFIELD INSTITUTE	BIOGEN IDEC - 483 3/15/13